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## Staying Within the Negotiated Framework: Abiding by the Non-Discrimination Clause in Trips Article 27

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## STUDENT NOTE

# STAYING WITHIN THE NEGOTIATED FRAMEWORK: ABIDING BY THE NON-DISCRIMINATION CLAUSE IN TRIPS ARTICLE 27

*Kevin J. Nowak\**

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## I. INTRODUCTION

The World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs)<sup>1</sup> has caused considerable

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1. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, WTO Agreement, Annex 1C, Legal Instruments-Results of the Uruguay Round, vol. 31, 33 I.L.M. 81 (1994) (TRIPs Agreement).

debate since its formal adoption in the Uruguay Round of 1994 as scholars try to understand its text and legal implications.<sup>2</sup> Not surprisingly, like many other WTO agreements, TRIPs is a compromise between countries with countervailing interests and therefore, is very disjunctive—containing many seemingly contradictory standards.<sup>3</sup> Such disjunction makes the relationship between various parts of the treaty difficult to understand and creates many separate balancing tests within the agreement itself.<sup>4</sup> Its purposefully vague language has formalized some aspects of intellectual property rights, but has also created questions in many other areas.<sup>5</sup> Section 5 Patents is an epicenter for the academic debates arising from TRIPs, especially in the realm of pharmaceutical products.<sup>6</sup> The breadth of scope and coverage of Section 5 in addressing the issues and conflicts of both developed and non-developed states has made TRIPs “the most important multilateral instrument in this field.”<sup>7</sup>

Article 27 has probably been the greatest source of controversy between developed and non-developed Members arising out of the TRIPs Agreement, especially regarding the availability of generic medicines to combat AIDS and other medical crises.<sup>8</sup> One debate arising from the negotiated language of Article 27 is the purported implications of its broad non-discrimination clause.<sup>9</sup> The interaction between Articles 27, 28, 30, and 31 holds the answer to which intellectual property rights a government must enforce and those it can forego in the pursuit of government policies that will most benefit its people.<sup>10</sup> These policies include every-

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2. Zhang Naigen, *Dispute Settlement Under the TRIPS Agreement from the Perspective of Treaty Interpretation*, 17 TEMP. INT'L & COMP. L.J. 199, 200 (2003) (stating that as of 2003 “more than twenty disputes have arisen under the TRIPs Agreement since it was entered into force on January 1, 1995”).

3. WORLD TRADE ORGANIZATION, PHARMACEUTICAL PATENTS AND THE TRIPS AGREEMENT, at [http://www.wto.org/english/tratop\\_e/trips\\_e/pharma\\_ato186\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm) (TRIPs Technical Note) explaining that balancing the many different and often opposite interests of the Member States is very difficult.

4. WORLD TRADE ORGANIZATION, PHILOSOPHY: TRIPS ATTEMPTS TO STRIKE A BALANCE, at [http://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm00\\_e.html](http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm00_e.html) (TRIPs Fact Sheet).

5. See CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS 50 (2000).

6. Erin K. Bender, *North and South: The WTO, TRIPS, and the Scourge of Biopiracy*, 11 TULSA J. COMP. & INT'L L. 281, 309 (2003).

7. DANIEL J. GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS, 220 (1998).

8. Bender, *supra* note 6, at 311.

9. Paul Champ & Amir Attaran, *Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patents Dispute*, 27 YALE J. INT'L L. 365, 368 (2002).

10. IAN McTAGGERT SINCLAIR, THE VIENNA CONVENTION ON LAW OF TREATIES 127 (2D ED. 1984) “The text of a treaty must be read as a whole. One cannot simply concentrate on

thing from economic growth<sup>11</sup> to the compulsory licensing of medicines used to stem a health crisis.<sup>12</sup> In *Canada—Patent Protection of Pharmaceutical Products (Canada—Generic Medicines)*, the Panel found that the non-discrimination clause in Article 27 applied to exceptions granted under Articles 30 and 31.<sup>13</sup> Many scholars disagree with the Panel's decision because they believe that applying the non-discrimination clause to Articles 30 and 31 will unfairly limit the ability of governments to pursue the policies they find most fit for their people and that such a limitation would be most detrimental to least developed and developing countries, forcing them to fall further behind in the technological realm, particularly in the ability to provide essential medicines at a reduced price.<sup>14</sup> This scholarly group argues in various ways that Articles 30 and 31 provide total exceptions to the Section 5, allowing States to deny patent rights and avoid possible conflicts with the Article 27 non-discrimination clause.<sup>15</sup>

This Note argues that the Panel in *Canada—Generic Medicines* correctly decided that the non-discrimination clause in Article 27 applies to the exceptions of Articles 30 and 31. Because Article 27 is the guiding force of Section 5, any exceptions to the rights granted under Section 5 must comply with the requirements set forth in Article 27.<sup>16</sup> Although extreme applications of the non-discrimination clause could be limiting upon some exceptions, Articles 30 and 31 were not placed into TRIPs as complete escape clauses from the framework of Section 5.<sup>17</sup> Additionally, the application of the non-discrimination clause to Articles 30 and 31 are not necessarily as limiting as some scholars fear—the negotiated text provides a number of methods Members can use to alleviate most constraints.<sup>18</sup>

Part II of this Note provides an introduction to the TRIPs Agreement and lays out the interpretation standard used. Part III discusses the

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a paragraph, an article, a section, a chapter, or a part." Champ & Attaran, *supra* note 9, at 383. ("Only by reading these provisions as a whole can the meaning of Article 27(1) be determined. This more inclusive approach accords with established principles of treaty interpretation.").

11. ROBERT L. OSTERGARD JR., THE DEVELOPMENT DILEMMA: THE POLITICAL ECONOMY AND INTELLECTUAL PROPERTY RIGHTS IN THE INTERNATIONAL SYSTEM 45 (2003).

12. Johanna Kiehl, *TRIPS Article 31(B) and the HIV/AIDS Epidemic*, 10 J. INTELL. PROP. L. 143, 143 (2002).

13. *Canada—Patent Protection of Pharmaceutical Products (Canada—Generic Medicines)*, Mar. 20, 2000, DSR 2000:V 2289, WTO Doc. WT/DS114/R ¶¶ 7.91, 7.93. See *infra* Parts V(B) and VI for dissenting scholarly work.

14. Champ & Attaran, *supra* note 9; Bender, *supra* note 6.

15. Champ & Attaran, *supra* note 9, at 367.

16. See *infra* Parts III, V, and VI.

17. See *infra* Part V.B.

18. See *infra* Parts III and V.D.

Dispute Resolution Body's (DSB) interpretation of Articles 27 and 30 as explained by the Panel in *Canada—Generic Medicines*. Part IV describes the Doha Declaration, which is the WTO's response to the Member State's concerns regarding the availability of generic medicines, and analyzes its practical effects on Articles 27 and 30. Part V turns to a strict textual analysis of Articles 27, 28, and 30 and incorporates the understandings of the DSB into the text. With the necessary information having been laid out, Part V focuses on the interaction between Articles 27 and 30. Part VI explains the interaction within the TRIPs Agreement as a whole, the text of the Articles, the understanding of the Member States at the time of agreement, and how the Members can avoid the proposed limitations caused by a broad interpretation of Article 27.

## II. INTELLECTUAL PROPERTY RIGHTS INSTITUTIONALIZED: TRIPs

The WTO defines intellectual property rights (IPRs) as "the rights given to people over the creations of their minds. They usually give the creator an exclusive right over the use of his/her creations for a certain period of time."<sup>19</sup> Patents safeguard a certain type of IPRs designed to protect "industrial property protected primarily to stimulate innovation, design and the creation of technology" which includes inventions, industrial designs, and trade secrets.<sup>20</sup>

Pre-TRIPs, Member States maintained widely varying levels of IPR protection and enforcement to protect their divergent "goals, values, history, culture, tradition and political climate . . ."<sup>21</sup> The pre-TRIPs system led some countries to provide very little protection.<sup>22</sup> Most international IPR protection was derived from a number of bi-lateral and multi-lateral trade agreements.<sup>23</sup> This arrangement led to many differences in the way countries protected IPRs and did not provide for a binding enforcement mechanism.<sup>24</sup> The United States and other developed countries sought a more uniform and institutionalized system of IPRs to ensure maximum protection for their products, predictability of local market rules, and a

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19. WORLD TRADE ORGANIZATION, PHARMACEUTICAL PATENTS AND THE TRIPs AGREEMENT, at [http://www.wto.org/english/tratop\\_e/trips\\_e/pharma\\_ato186\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm) (TRIPs FAQs).

20. *Id.*

21. Donald P. Harris, *TRIPs' Rebound: An Historical Analysis of How the TRIPs Agreement Can Ricochet Back Against the United States*, 25 N.W. J. INT'L L. & BUS. 99, 104 (2004).

22. *Id.*

23. Bryan C. Mercurio, *TRIPs, Patents, and Access to Life-Saving Drugs in the Developing World*, 8 MARQ. INTELL. PROP. L. REV. 211, 215–17 (2004).

24. *Id.*

central dispute settlement mechanism.<sup>25</sup> Developing countries were hesitant to adopt a central institutionalized forum because they believed this type of forum was most favorable to developed countries and would not adequately consider their needs and interests.<sup>26</sup>

The final TRIPs Agreement addresses five main issues:

- (1) how basic principles of the trading system and other international intellectual property agreements should be applied;
- (2) how to give adequate protection to intellectual property rights;
- (3) how countries should enforce those rights adequately in their own territories;
- (4) how to settle disputes on intellectual property between members of the WTO;
- (5) special transitional arrangements during the period when the new system is being introduced.<sup>27</sup>

Under TRIPs, intellectual property refers to "all categories of intellectual property that are the subject of Sections 1 through 7 of Part II."<sup>28</sup> These rights include: copyright and related rights; trademarks; geographical indications; industrial designs; patents; layout-designs (topographies) of integrated circuits; and protection of undisclosed information.<sup>29</sup> In addressing those issues, TRIPs "establishes minimum levels of protection that each government has to give to the intellectual property of fellow WTO members."<sup>30</sup> As a minimum standards agreement, TRIPs "allows states to give greater protection to intellectual property rights if they choose."<sup>31</sup> It also allows Member States to implement the Agreement in the way they deem proper within their legal system.<sup>32</sup> To establish the

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25. MICHAEL J. TREBILCOCK & ROBERT HOWSE, *THE REGULATION OF INTERNATIONAL TRADE* 320 (2nd ed. 1999); Ruth L. Okediji, *Public Welfare and the Role of the WTO: Reconsidering the TRIPS Agreement*, 17 EMORY INT'L L. REV. 819, 842-43 (2003). A coalition of forty countries supported TRIPs and ensured its adoption by the Ministerial Conference in Punta del Este.

26. Champ & Attaran, *supra* note 9, at 373.

27. World Trade Organization, *Intellectual Property: Protection and Enforcement*, at [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/agrm7\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm) (hereinafter *IP Protection and Enforcement*).

28. TRIPs Agreement, *supra* note 1, art. 1.2.

29. *Id.* §§ 1-7.

30. *IP Protection and Enforcement*, *supra* note 27.

31. Muria Kruger, *Harmonizing TRIPs and the CBD: A Proposal from India*, 10 MINN. J. GLOBAL TRADE 169, 179 (2001).

32. TRIPs FAQs, *supra* note 19; see also Declaration on the TRIPs Agreement and Public Health, Nov. 14, 2001, WTO Doc. WT/MIN(01)/DEC/2, 5(b)(Doha Declaration). The Doha Declaration reaffirms several commitments of the TRIPs Agreement (discussed *infra*,

minimum levels, TRIPs incorporates the “substantive obligations” of WIPO, the Paris Convention, and the Berne Convention (excluding the moral rights in Berne) and select provisions of the Treaty on Intellectual Property in Respect of Integrated Circuits and the Rome Convention with “additional obligations in areas which were not addressed in these conventions, or were thought not to be sufficiently addressed in them.”<sup>33</sup> TRIPs establishes baseline international standards for pharmaceutical protection and attempts to balance the short term objectives of affording access to medicines and the long term objective of providing incentives for the development of new medicines.<sup>34</sup>

As part of the final compromise on TRIPs, the Member States allowed for an extended transitional period until January 2006 for the least developed countries and a number of exceptions to the general rules of the agreement, including the continued allowance of compulsory licensing for patents under Article 31.<sup>35</sup> TRIPs also established the first centralized dispute settlement mechanism for disagreements involving intellectual property matters by subjecting those disagreements to the WTO’s dispute settlement procedures.<sup>36</sup> One scholar notes: “As is the case with many international agreements negotiated by diplomats, the agreement has both textual and operational flaws, but finally did achieve a system of worldwide uniform intellectual property protection through developed standards backed by the prospects of binding dispute resolution.”<sup>37</sup>

Before moving forward, it is proper to explain the standard used by the DSB when interpreting treaties and specifically TRIPs. The DSB settles all disputes regarding the TRIPs Agreement in accordance with the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU), which means any dispute under TRIPs will involve an examination of the consistency of a Member State’s domestic intellectual property laws with TRIPs.<sup>38</sup> Though TRIPs does not expressly name the Vienna Convention as the standard for interpreting its provisions, the DSB adopted the Vienna standard in its first Report and has followed it

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Part IV) including a Member State’s right to implement TRIPs in a manner appropriate to its legal system.

33. TRIPs FAQs, *supra* note 19.

34. Mercurio, *supra* note 23, at 218.

35. Doha Declaration, *supra* note 32 (the Doha Declaration pushed back the deadline for least developed and developing countries to 2016); *IP Protection and Enforcement*, *supra* note 27; TRIPs FAQs, *supra* note 19. Mercurio, *supra* note 23, at 218–19.

36. TRIPs FAQs, *supra* note 19.

37. Mercurio, *supra* note 23, at 218.

38. Naigen, *supra* note 2, at 201.

since the *United States—Gasoline* case.<sup>39</sup> The Vienna Convention standard is: “A treaty is to be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.”<sup>40</sup> To understand the meaning of a treaty in its entirety, the parties should use the express text, including its preamble and annexes, any agreements made by all parties in connection with the conclusion of the treaty, and any instrument connected to the conclusion of a treaty that is accepted by all the other parties as an instrument of the treaty.<sup>41</sup> Under Article 31(3) of the Vienna Convention, any subsequent agreement, practice, or special meaning intended can be used in addition to the text of the treaty to determine the “ordinary meaning” of the terms.<sup>42</sup> When the meaning of a term is still ambiguous, obscure, or “leads to a result which is manifestly absurd or unreasonable” after the application of Article 31, the parties may use “supplementary means of interpretation” such as the negotiating history to help determine the true meaning.<sup>43</sup> Words not present within a treaty, however, may not be assumed or imported into it.<sup>44</sup> The WTO Appellate Body has stated that it does not “condone the imputation into a treaty of words that are not there.”<sup>45</sup>

### III. CANADA—GENERIC MEDICINES: THE CURRENT DSB INTERPRETATION OF THE NON-DISCRIMINATION CLAUSE IN TRIPS ARTICLE 27

As previously mentioned, the Panel decision in *Canada—Generic Medicines* established the current DSB interpretation of the non-discrimination clause in Article 27. The question presented in the dispute was whether two provisions of Canada’s Patent Act were in conformity with Canada’s obligations under TRIPS.<sup>46</sup> The two disputed provisions, Sections 55.2(1) and 55.2(2) of the Patent Act, created exceptions to the

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39. Panel Report, *United States—Standards for Reformulated and Conventional Gasoline* (United States—Gasoline), adopted May 20, 1996, as modified by the Appellate Body Report, DSR 1996: I 29, WTO Doc. WT/DS2/R; Naigen, *supra* note 2, at 202.

40. Vienna Convention on the Law of Treaties, opened for signature May 23, 1969, art. 31(1), 1155 U.N.T.S. 331, 8 I.L.M. 679 (hereinafter Vienna Convention).

41. *Id.* art. 31(2).

42. *Id.* art. 31(3).

43. *Id.* art. 32.

44. *Id.* art. 31.

45. Appellate Body Report, *India—Patent Protection of Pharmaceutical and Agricultural Chemical Products* (India—Pharmaceuticals), adopted Jan. 16, 1998, DSR 1998:19, WTO Doc. WT/DS50/AB/R.

46. Canada—Generic Medicines, *supra* note 13, ¶ 7.1.



exclusive rights of patent owners.”<sup>47</sup> Section 55.2(1), known as the “regulatory review exception,” “applies to patented products such as pharmaceuticals whose marketing is subject to government regulation in order to assure their safety or effectiveness.”<sup>48</sup> The purpose of this exception is to “permit potential competitors of the patent owner to obtain government marketing approval during the term of the patent, so that they will have regulatory permission to sell in competition with the patent owner by the date on which the patent expires.”<sup>49</sup> Without the “regulatory review exception,” the patent holder could maintain exclusive control of the market for years beyond the cessation of its monopoly rights because the law would otherwise prevent competitors from using the patented product for testing purposes.<sup>50</sup> This exception has a limited scope, applying only to activities “solely for uses reasonably related to the development and submission of information required” by any law, Canadian or non-Canadian, that “regulates the manufacture, construction, use or sale of any product.”<sup>51</sup> According to data supplied by the Canadian government, a pharmaceutical product patent lasts twenty years, and of those twenty years, the drug company uses eight to twelve years to achieve regulatory approval, leaving twelve to eight years of actual market monopoly.<sup>52</sup> The regulatory and development process for a generic supplier is about three to six and one half years, meaning that if the patent holder were allowed to block any testing or development of the generic product until after the patent term had expired, the default patent term would become approximately twenty-three to twenty-six and one half years.<sup>53</sup> Canada, by its regulatory review exception, wished to remove the extra three to six and one half years from the process so as to more quickly provide less expensive medicine and competition.<sup>54</sup>

Section 55.2(2), known as the “stockpiling exception,” permits “competitors to manufacture and stockpile patented goods during a certain period before the patent expires, but the goods cannot be sold until

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47. *Id.*

48. *Id.* ¶ 7.2.

49. *Id.* The question arises whether the Canadian government is not enforcing the exclusive use of the patented product when it allows a competitor to test its copied versions of the patented product during the patent term.

50. *Id.*

51. *Id.* ¶ 7.5. Such a limitation is important because it shows that the Canadian government would only allow competitors to take the steps necessary to compete after the patent period was complete—which is the obligation of WTO Members, minus certain exceptions.

52. *Id.* ¶ 7.3.

53. *See id.*

54. *Id.* ¶¶ 7.2–7.3. The Canadian government has a strong interest to ensure that the healthcare costs of its citizens remain as low as possible. A good way to decrease costs is to ensure that the patents are strictly limited to the minimum standards established by TRIPs.

the patent expires.”<sup>55</sup> This exception allows for an imitator company to “make, construct, or use” a patented product during the patent term so the company may accumulate enough product to make a significant impact on the market once the patent holder’s exclusive rights have run out.<sup>56</sup> The exception in Section 55.2 needs implementing legislation to take effect and the Canadian government has passed such legislation for pharmaceuticals.<sup>57</sup> Additionally, Sections 55.2(1) and 55.2(2) are interconnected so that the only way a company could benefit from the Section 55.2(2) “stockpiling exception” was by first being approved for a “regulatory review exception” under Section 55.2(1).<sup>58</sup> If the Canadian government did not have both exceptions and tie them together, the exceptions would do very little independently in furtherance of their main purpose.<sup>59</sup> A hypothetical situation where a company would have the ability to stockpile a large quantity of products before the expiration of the patent term under Section 55.2(2), but not have permission to seek regulatory approval as provided under Section 55.2(1) would not promote the government’s purpose because few if any companies would be willing to take the risk of producing a large amount of product without knowing whether they could actually sell it.<sup>60</sup>

The European Community (EC) brought suit alleging “that Sections 55.2(1) and 55.2(2) of Canada’s Patent Act are inconsistent with Canada’s obligations under Articles 27.1 and 28.1 of the TRIPS Agreement and, to the extent that Section 55.2(2) violates Article 28.1, it is also inconsistent with Article 33 of the TRIPS Agreement.”<sup>61</sup> The EC claimed that their pharmaceutical industry had lost around C\$100 million per year because of the Canadian laws.<sup>62</sup> Beginning with its arguments against the “stockpiling exception” under Section 55.2(2), the EC made a number of claims. The EC’s first claim was that Canada violated its obligations under Articles 28.1 and 33 by permitting the manufacture and stockpiling of pharmaceuticals during the six months immediately before the expiration of the twenty year patent term.<sup>63</sup> The EC argued

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55. *Id.* ¶ 7.7. This is an even greater exclusive use problem since the section expressly allows a competitor to produce the replicated product during the patent term of the patent owner.

56. *Id.*

57. *Id.* ¶ 7.8. Again, the Canadian government is striving to ensure that upon the expiration of the twenty year patent term a generic replication would be available, and furthermore, a company could manufacture a significant enough stock to have a substantial and continuous impact on the market beginning on the first day after the twenty years elapse.

58. *Id.* ¶ 7.10.

59. *Id.*

60. *See id.*

61. *Id.* ¶ 7.11.

62. *Id.* ¶ 4.7.

63. *Id.* ¶ 4.2.

that Canada violated its agreement to provide patent protection for twenty years by allowing a company to stockpile six months early, thereby providing only nineteen and one half years protection; anybody was allowed to make the replicated products six months before the expiration of the patent without the consent of the patent holder; and Canada was the only country in the world that allowed for such an exception.<sup>64</sup> Secondly, "by treating patent holders in the field of pharmaceutical inventions less favourably than inventions in all other fields of technology, Canada infringed its obligations contained in Article 27.1 of the TRIPS Agreement."<sup>65</sup> The EC contended that Section 55.2(2) discriminated by field of technology because pharmaceuticals were the reason that Section 55.2(2) passed and did not apply to any other product; and "the Canadian legislation discriminated against pharmaceutical inventions by treating them less favourably than inventions in all other fields of technology . . ."<sup>66</sup>

After discussing the "stockpiling exception," the EC explained its objections to the "regulatory review exception" in Section 55.2(1). The EC believed that Section 55.2(1) "allowed all activities related to the development and submission of information required to obtain marketing approval for pharmaceutical products carried out by a third party without the consent of the patent holder at any time during the patent term, notwithstanding the exclusive rights stipulated in Article 28.1"<sup>67</sup> Furthering this argument, the EC contended that the lack of time limitation was unacceptable; almost all the exclusive rights of a patent owner were removed with a very limited exception; and the interaction of Sections 55.2(1) and 55.2(2) allowed an almost unlimited violation of the exclusive rights of making and using a product during the patent term.<sup>68</sup> After all, Section 55.2(1) allowed companies to buy and sell the patented product without the patent holder's permission as long as it was "reasonably related to the development and submission of information required under the law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product."<sup>69</sup> Secondly, the EC contended that by allowing the developmental and regulatory process on a copied product to proceed during the

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64. *Id.* Articles 28 and 33 confer the exclusive rights of a patent holder. Article 33 guarantees that a patent term extends to twenty years from the filing date. Article 28 guarantees certain rights for the patent holder including exclusive use and making of the product.

65. *Id.* ¶ 4.3.

66. *Id.*

67. *Id.* ¶ 4.4.

68. *Id.* The combination of exceptions does allow a company a lot of leeway to copy and make a product during the patent term which unquestionably is a violation of the express requirements of Article 28.

69. *Id.*

patent term “without the consent of the patent holder at any time during the patent term, Canada treated holders of pharmaceutical patents less favourably than holders of patents in all other fields of technology and thus violated its obligations under Article 27.1.”<sup>70</sup> They further maintained that even though the text of the regulation applied to all fields of technology, in practice it only applied to pharmaceuticals.<sup>71</sup>

A final issue addressed by the EC that is pertinent to this Note is the application of Article 30 to this dispute.<sup>72</sup> As discussed below, Canada invoked Article 30 as a defense to its regulations because, as it argued, though the exceptions might have been a violation of Article 28, its regulations were narrow enough to fall under the “limited exceptions” of Article 30.<sup>73</sup> The EC disagreed with Canada’s defense arguing that the exceptions provided in the regulations were not “limited exceptions” and that “a violation of Article 27.1 of the TRIPS Agreement could not be justified under Article 30.”<sup>74</sup>

Canada disagreed with the EC’s interpretation of Article 30 and stated that the exceptions provided for in Sections 55.2(1) and 55.2(2) to the exclusive rights of the patent holder were limited exceptions, did not conflict with the “normal exploitation” of a patent, did not prejudice or unreasonably prejudice the “legitimate interests” of the patentee or third parties, and the third party interests taken into account “were ‘legitimate interests’ of relevant third parties.”<sup>75</sup> Furthering this line of reasoning, Canada also claimed that “the prohibition in *Article 27.1 of the TRIPS Agreement* against discrimination on the basis of field of technology did not apply to allowable limited exceptions.”<sup>76</sup> Even if Article 27.1 does apply to allowable limited exceptions, Canada claimed it “did not discriminate as to the field of technology in which an invention occurred, because they related to products that were subject to laws regulating the manufacture, construction, use or sale of a product and were not expressly related to any particular field of technology.”<sup>77</sup> Canada also denied the contention that allowing exceptions amounted to a violation of the twenty year patent term guaranteed under Article 33 “because they

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70. *Id.* ¶ 4.5.

71. *Id.*

72. *Id.* ¶ 4.8.

73. *Id.*

74. *Id.*

75. *Id.* ¶ 4.9.

76. *Id.*

77. *Id.* The actual regulation did not contain a clause limiting the application of the regulation to pharmaceuticals. However, the only product area in which the Canadian legislature had actually passed implementing legislation was pharmaceuticals. This closely reflects the EC contention that the regulation was not discriminatory on its face, but it was discriminatory in enforcement.

did nothing to impair a patentee's right to exploit its patent for the full term of protection by working the patent for its private commercial advantage."<sup>78</sup> Interestingly, "Canada acknowledged that the provisions of Section 55.2(2) permitting third parties to 'make,' 'construct,' or 'use' the patented product during the term of the patent, without the patent owner's permission, would be a violation of Article 28.1 if not excused under Article 30 of the Agreement."<sup>79</sup>

After considering the positions of the EC, Canada, and eleven third parties, the Panel concluded that Canada's only violation was that "Section 55.2(2) of Canada's *Patent Act* is not consistent with the requirements of Article 28.1."<sup>80</sup> The Panel then asked the Dispute Settlement Body to "request that Canada bring Section 55.2(2) into conformity with Canada's obligations under the TRIPS Agreement."<sup>81</sup> Additionally, the Panel decided not to discuss the EC's claim that Articles 28.1 and 33 were interconnected, directly addressing only the Article 28 violation at this time.<sup>82</sup> Surprisingly, despite Canada's winning on the 55.2(1) claims, the Panel ruled against most of its legal arguments.<sup>83</sup>

Most important for this Note, the Panel stated that it "was unable to agree with Canada's contention that Article 27.1 did not apply to exceptions granted under Article 30. The text of the TRIPS Agreement offers no support for such an interpretation."<sup>84</sup> The Panel further explained that:

Article 27.1 prohibits discrimination as to enjoyment of "patent rights" without qualifying that term. Article 30 exceptions are explicitly described as "exceptions to the exclusive rights conferred by a patent" and contain no indication that any exemption from non-discrimination rules is intended. A discriminatory exception that takes away enjoyment of a patent right is discrimination as much as is discrimination in the basic rights

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78. *Id.* Essentially, Canada argued that the generic drug companies were not benefiting during the patent term because they could not sell the product until after the twenty years were up. It is only fair to the consumer market that immediately after the twenty year patent term is completed a competitor could actively compete. Otherwise, the patent holder would receive a de facto three to six and one half year extension on its monopoly rent which is the average time estimate for the regulatory approval of a generic medicine in Canada.

79. *Id.* ¶ 7.18.

80. *Id.* ¶ 8.1.

81. *Id.*

82. *Id.* ¶ 7.38. The Panel did not find the need to address Article 33 questions because it found that Section 55.2(2) did not fulfill the first requirement of Article 30 and therefore, they did not have to address the rest of the claims.

83. *Id.* ¶¶ 7.39–7.84. Perhaps the most significant argument that Canada lost under this section of the opinion is the scope of Article 30's limited exceptions. These differences are discussed under the interpretation of Article 30, *infra*, Parts V(B) and VI.

84. *Id.* ¶ 7.91.

themselves. The acknowledged fact that the Article 31 exception for compulsory licences and government use is understood to be subject to the non-discrimination rule of Article 27.1, without the need for any textual provision so providing, further strengthens the case for treating the non-discrimination rules as applicable to Article 30. Articles 30 and 31 are linked together by the opening words of Article 31 which define the scope of Article 31 in terms of exceptions not covered by Article 30.<sup>85</sup>

The Panel also disagreed with Canada's policy arguments that its ability under the Patent Act to discriminate against individual patents made its exceptions to Article 30 limited and that applying Article 27 to Article 30 exceptions would force those exceptions to apply to all products.<sup>86</sup> First, "an Article 30 exception cannot be made 'limited' by limiting it to one field of technology, because the effects of each exception must be found to be 'limited' when measured against each affected patent."<sup>87</sup> Secondly:

Article 27 prohibits only discrimination as to the place of invention, the field of technology, and whether products are imported or produced locally. Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas. Moreover, to the extent the prohibition of discrimination does limit the ability to target certain products in dealing with certain of the important national policies referred to in Articles 7 and 8.1, that fact may well constitute a deliberate limitation rather than a frustration of purpose. It is quite plausible, as the EC argued, that the TRIPS Agreement would want to require governments to apply exceptions in a non-discriminatory manner, in order to ensure that governments do not succumb to domestic pressures to limit exceptions to areas where right holders tend to be foreign producers.<sup>88</sup>

The Panel did not find Canada's general legal and policy arguments regarding the interaction of Articles 27 and 30 persuasive, but it agreed with Canada's arguments on their own alleged discrimination in finding that Canada's statute did not violate the non-discrimination clause of

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85. *Id.* The Panel's very textual approach to understanding the relationship between the individual provisions of TRIPs follows closely to the rules mandated by the Vienna Convention in Article 31(1) "A treaty is to be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose."

86. *Id.* ¶ 7.92.

87. *Id.*

88. *Id.*

Article 27.<sup>89</sup> Section 55.2(1) engaged in neither *de jure* nor *de facto* discrimination against pharmaceutical products.<sup>90</sup> “It was not proved that the adverse effects of Section 55.2(1) were limited to the pharmaceutical industry, or that the objective indications of purpose demonstrated a purpose to impose disadvantages on pharmaceutical patents in particular.”<sup>91</sup>

The question then becomes to what extent Article 27.1 limits the exceptions under Article 30 and Article 31. After all, at first glance, an article that guarantees absolute non-discrimination by field of technology could limit many exceptions into non-existence—especially compulsory licenses. The Panel did not rule against Canada in this case even though the Panel stated it was clear that “the primary reason for passing the measure was its effect on promoting competition in the pharmaceutical sector. This is also evident from Canada’s justification for the measure presented in this dispute settlement proceeding.”<sup>92</sup> The Panel further stated:

[P]reoccupation with the effects of a statute in one area does not necessarily mean that the provisions applicable to other areas are a sham, or of no actual or potential importance. Individual problems are frequently the driving force behind legislative actions of broader scope. The broader scope of the measure usually reflects an important legal principle that rules being applied in the area of primary interest should also be applied to other areas where the same problem occurs. Indeed, it is a common desideratum in many legal systems that legislation apply its underlying principles as broadly as possible. So long as the broader application is not a sham, the legislation cannot be considered discriminatory. In the absence of any proof that the broader scope was a sham, it must be found that the evident concentration of public attention upon the effects of Section 55.2(1) on the pharmaceutical industry is not, by itself, evidence of a discriminatory purpose.<sup>93</sup>

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89. *Id.* ¶ 7.105.

90. *Id.*

91. *Id.*

92. *Id.* ¶ 7.104. The language of the statute did not single out pharmaceutical patents, but the legislators who enacted 55.2(1) clearly penned this provision in reaction to a perceived need of less expensive pharmaceutical products.

93. *Id.* Section 55.2(1) does not expressly mention the pharmaceutical industry and applies “solely for uses reasonably related to the development and submission of information required under any law [. . .] that regulates the manufacture, construction, use or sale of any product”. *Id.* ¶ 7.95. Thus, any product that requires regulatory approval including “agricultural chemicals, foodstuffs, cosmetics, automobiles, vessels and aircraft” falls within the scope of this regulation. *Id.*

The *Canada—Generic Medicines* Panel crafted its language very carefully so as to avoid creating a situation in which a State would be in violation of Article 27 if it needed to grant an Article 30 exception for a particular product.<sup>94</sup> It also provided great leniency on the purposes for which legislation may be passed and not considered discriminatory.<sup>95</sup> The next section further illustrates the WTO's understanding of Articles 27 and 30 and its awareness of the potential problems caused by an overly restrictive standard on the use of exceptions.

#### IV. THE DOHA DECLARATION: THE MEMBER STATES EXPRESSING THEIR CONCERNS

The Doha Declaration on the TRIPs Agreement and Public Health directly addressed some of the concerns of WTO Member States regarding the perceived limitations caused by Section 5 on their ability to provide adequate pharmaceuticals to their population.<sup>96</sup> It is viewed as the "first significant victory for developing countries in the short history of TRIPS" and was also "a major success for the highly visible international activist movement that has long campaigned against poor access to pharmaceuticals in developing countries."<sup>97</sup> "The final text of the Doha Declaration sought to 'clarify' the interpretation of TRIPs and emphasized the 'flexibilities' already written into the agreement, including the right of Members to invoke those provisions when needed."<sup>98</sup> Paragraphs 1–3 of the Declaration recognize the concerns of both developing countries in their desire to provide medicine for their populace as well as the

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94. *Id.* ¶ 7.92. As quoted above, the Panel expressly said that "Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas."

95. *See id.* ¶ 7.104.

96. Doha Declaration, *supra* note 32; Amir Attaran, *The Doha Declaration on the TRIPs Agreement and Public Health, Access to Pharmaceuticals, and Options Under WTO Law*, 12 FORDHAM INTELL. PROP. MEDIA AND ENT. L.J. 859, 860 (2002).

97. Mercurio, *supra* note 23, at 212. The timing of the Doha Declaration is not coincidental:

The time was ripe for developing countries to push for a shift in stance from developed countries towards access to medicines. Not only did the highly visible plight of many poor and ravaged countries place a significant amount of pressure on developed nations to be sympathetic to the demands of developing countries and the LDCs, but the U.S. and Canada faced the possibility of looking extremely hypocritical in the wake of its post-September 2001 threats [i.e. the U.S. government threatening to issue a compulsory license against Bayer AG Corporations Cipro antibiotic, which is a treatment for anthrax].

*Id.*

98. *Id.* at 225.



desire of developed countries to provide intellectual property protection for their corporations.<sup>99</sup> Paragraph 4 declares that the Ministers:

agree that the TRIPS agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Member's right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.<sup>100</sup>

Thus, "Paragraph 4 strongly reaffirms the principle that protecting public health and promoting access to medicines is a valid basis for Members to enact exceptions to patent protection in their domestic legislation."<sup>101</sup> Paragraph 5 lists "flexibilities" Members may use in implementing TRIPs.<sup>102</sup> Paragraph 5 states:

Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include (a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles. (b) Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted. (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relation to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency. (d) The effect of the provision in the TRIPS Agreement that are relevant

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99. Doha Declaration, *supra* note 32, ¶¶ 1–3; Mercurio, *supra* note 23, at 226. Paragraph 1 "recognize[s] the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics." Paragraph 2 "stress[es] the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems." Paragraph 3 "recognize[s] that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices." Doha Declaration, *supra* note 32 ¶¶ 1–3.

100. Doha Declaration, *supra* note 32, ¶ 4.

101. Mercurio, *supra* note 23, at 226.

102. Doha Declaration, *supra* note 32, ¶ 5; Mercurio, *supra* note 23, at 226–27.

to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.<sup>103</sup>

Paragraph 6 discusses the availability of compulsory licenses in countries “with insufficient or no manufacturing capabilities in the pharmaceutical sector” and directs the Council for TRIPs to find a solution.<sup>104</sup> Paragraph 7 extends the application of TRIPs Sections 5 and 7 for least developed countries until January 1, 2016.<sup>105</sup>

Although the Doha Declaration called for greater flexibility in the use of TRIPs to further the availability of medicines, the Declaration and ensuing implementation of Paragraph 6 did not provide unrestricted usage of the exceptions to TRIPs.<sup>106</sup> The Doha Declaration does not restrict the use of the DSB, except in challenging the exhaustion of IPRs standards of other Members, so States may still enforce their IPRs before a binding authority.<sup>107</sup> The Ministers rejected the attempts of developing countries to add language into the Declaration stating: “nothing in the TRIPs Agreement prevents Members from granting compulsory licenses to foreign suppliers to provide medicines in the domestic markets” and “nothing in the TRIPs Agreement will prevent Members to grant compulsory licenses to supply foreign markets.”<sup>108</sup> The Ministers also rejected proposals by the developing countries and a group of NGO’s to use the limited exceptions of Article 30 to allow producer countries to manufacture and export patented medicines to countries in a health crisis even though the pharmaceutical is patented in the producer country.<sup>109</sup> In arguing against such an amendment, developed countries successfully maintained that using an Article 30 approach to permit discrimination against the pharmaceutical industry may run afoul with the requirements of Article 27 to not discriminate as to the field of technology.<sup>110</sup> The

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103. Doha Declaration, *supra* note 32, ¶ 5.

104. *Id.*, ¶ 6.

105. *Id.*, ¶ 7.

106. *Id.* ¶¶ 4–5. “Ministerial Declarations are not binding of Members or the dispute settlement system, and the agreements negotiated by Members (WTO Agreement) would certainly prevail over the Doha Declaration, but the Declaration was careful to recognize this fact and the commitments in TRIPs do no seem to be contradictory to these commitments.” Mercurio, *supra* note 23, at 228 (footnotes omitted).

107. See generally Doha Declaration, *supra* note 32, ¶ 6; see also Mercurio, *supra* note 23, at 228.

108. Council for the Trade Related Aspects of Intellectual Property Rights, *Proposal on Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health*, June 24, 2002, WTO Doc. IP/C/W/351.

109. Mercurio, *supra* note 23, at 230–32.

110. *Id.*

proposals by the NGOs and developing countries may also conflict with the Article 4 Most Favoured Nation requirement if the country producing the lower priced drugs were to only make the drugs for nationals of developing countries and not developed countries.<sup>111</sup> A final reason that the Ministers probably did not adopt a new, express exception in the Declaration and resulting Implementation was because a new interpretation of Article 30 cannot be a covert amendment, but can only be an interpretation.<sup>112</sup> An official interpretation, as stated in Article IX:2 of the WTO Agreement, "shall not be used in a manner that would undermine the amendment provisions."<sup>113</sup> Because an official interpretation including a provision that on its face appears to violate Articles 4 and 27 would violate the amendment provisions, the Ministers could not approve it.<sup>114</sup>

Having detailed the rationale and history behind the current understanding of the interaction between Articles 27 and 30, the rest of this Note will explain why the non-discrimination clause in Article 27 guides the exceptions under Article 30 and that the exceptions under Article 30 are not as limited as they seem.

#### IV. MEET THE ARTICLES: AN INTRODUCTION TO THE ARTICLES IN CONTENTION

As mentioned earlier, Section 5 of the TRIPs Agreement sets the standards for the availability, scope, and use of patents for protection of IPRs.<sup>115</sup> This Part provides an introduction to the articles that are the main focus of this Note.

##### A. Article 27: Hegemon

Article 27.1 is the first paragraph of Section 5: Patents and mandates that "subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology provided that they are new, involve an inventive step and are capable of industrial application."<sup>116</sup> This seemingly limitless requirement to grant patents for inventions that meet all of the elements of the first sentence of Article 27.1 has an express internal check that sub-

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111. *Id.* at 233.

112. *Id.* at 234.

113. *Id.*

114. *Id.* at 234–35.

115. Notes 27–29, *supra*.

116. TRIPs Agreement, *supra* note 1, art. 27.1.

jects the clause to the limiting language of Articles 27.2 and 27.3.<sup>117</sup> The exclusions in Articles 27.2 and 27.3 are the only exceptions expressly named to apply to the availability of patents governed by Article 27.1 within the patents section.<sup>118</sup> Article 27.2 allows for States to exclude from patentability those inventions whose commercial exploitation are necessary to protect the “ordre public, or morality” of a country including life, health, and the environment.<sup>119</sup> This exclusion cannot be made “merely because the exploitation is prohibited by their law.”<sup>120</sup> *Ordre public* and morality are exceptions that allow for a State to decide if the commercial exploitation of a patent would violate that State’s fundamental social and ethical norms.<sup>121</sup> Since this is fundamentally a public policy exception, “TRIPs allows the state to decide for itself whether or not the prevention of commercial exploitation is ‘necessary,’” which means that theoretically a Member State does not have to consult other States when deciding whether to exclude a product or process from patentability.<sup>122</sup> TRIPs does limit, however, the actual independence of a Member’s decision because if a dispute over the exception arises, it still falls under Panel scrutiny.<sup>123</sup> Additionally, when attempting to apply this exception, a problem arises if a State is trying to use Article 27.2 to allow for the replication of a product or process by a local producer because the marketing of the item within the State’s boundaries must be completely outlawed, even to local producers.<sup>124</sup> The exception becomes even more narrowly applicable when determining what is “necessary.”<sup>125</sup> To be “necessary,” an exception must be the “least trade restrictive” possible, meaning there must be no other reasonably available alternatives to protect the *ordre public* or morality.<sup>126</sup> Thus, even though Article 27.2 is a public policy exception, it has a limited applicability because the terms

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117. *Id.* TRIPs allows for exclusions because patent protection is not a fundamental right, but rather one granted to promote public policy goals. Timothy G. Ackermann, *Dis'ordre'ly Loopholes: TRIPs Patent Protection, GATT, and the ECJ*, 32 TEX. INT'L L.J. 489, 494 (1997).

118. TRIPs Agreement, *supra* note 1, § 5.

119. *Id.* art. 27.2.

120. *Id.*

121. Ackermann, *supra* note 117, at 496.

122. *Id.* at 493.

123. *Id.* TRIPs cannot allow for complete Member State independence on an Article 27.2 determination because this could encourage sham determinations by countries trying to purposely avoid the TRIPs framework. By allowing third party recourse in the Panel, TRIPs encourages compliance with the Agreement.

124. George K. Foster, *Opposing Forces in a Revolution in International Patent Protection: The U.S. and India in the Uruguay Round and its Aftermath*, 3 UCLA J. INT'L L. & FOREIGN AFF. 283, 290 (1998).

125. Ackermann, *supra* note 117, at 507.

126. *Id.* (exploring the meaning of GATT XX(b) and using this meaning to derive the definition of “necessary” within Article 27.2).

are narrowly construed.<sup>127</sup> Under Article 27.3, Members may exclude from patentability “diagnostic, therapeutic, and surgical methods for the treatment of humans or animals.”<sup>128</sup> It also excludes “plants and animals other than micro-organisms” and “essentially biological processes for the production of plants or animals.”<sup>129</sup> Although this provision seems to grant developing countries substantial flexibility in the protection of plants and animals, “in practice this has not been the case.”<sup>130</sup> Article 27.3 “is intended to facilitate the dissemination of innovations in medical treatment methods,” not to allow for a Member State to refuse to patent pharmaceuticals.<sup>131</sup> Article 70.8 further supports this understanding by requiring Member States “to set up a means of collecting applications for pharmaceutical patents” because Article 70.8 would be unnecessary if Article 27.3 allowed the total exclusion of pharmaceuticals.<sup>132</sup> Additionally, many developed countries put intense pressure on developing countries to comply with the narrow understanding by threatening trade sanctions if a developing country were to formulate a broader understanding.<sup>133</sup>

Another express requirement for the availability of patents is the non-discrimination clause of 27.1 that states “Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be *available* and patent rights [shall be] *enjoyable* without discrimination as to the place of invention, the field of technology and whether the products are imported or locally produced.”<sup>134</sup> The word “discriminate” “is a normative term, pejorative in connotation, referring to results of the unjustified imposition of differentially disadvantageous treatment.”<sup>135</sup> Essentially, the clause establishes three genres of discrimination that are unlawful under TRIPs: (1) discrimination between

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127. *Id.* at 509.

128. TRIPs Agreement, *supra* note 1, art. 27.3.

129. *Id.*

130. Bender, *supra* note 6, at 310.

131. Foster, *supra* note 124, at 290.

132. *Id.*

133. Bender, *supra* note 6, at 311-12.

134. TRIPs Agreement, *supra* note 1, art. 27.1 (emphasis added); Champ & Attaran, *supra* note 9, at 386. Upon a careful reading of the Article, the “shall be” that falls between “patents” and “available” in the non-discrimination clause carries across the conjunction “and” so that the phrase “patent rights enjoyable” contains an understood “shall be.” Therefore, the non-discrimination clause should read “patents shall be available and patent rights [shall be] enjoyable.” Similarly to the first clause of Article 27, the non-discrimination clause is expressly limited by (1) Article 27.3, (2) paragraph 4 of Article 65, Transitional Arrangements, which discusses the extent a developing Member can delay implementing a patent system, and (3) paragraph 8 of Article 70, Protection of Existing Subject Matter, which creates the process for the amelioration of discrimination if the Member does not have a system for the protection of pharmaceuticals and agricultural chemical products at the time of entry.

135. Canada—Generic Medicines, *supra* note 13, at ¶ 7.94.

different fields of technology; (2) discrimination as to place of invention and; (3) discrimination between imported or locally produced products.<sup>136</sup> Denoted by the use of the word “and” between “available *and* patent rights enjoyable” as well as in the series “place of invention, the field of technology, *and* whether the products are imported or locally produced” a country must meet all six requirements to avoid violation of the non-discrimination clause.<sup>137</sup> Any action that discriminates as to the availability and enjoyability of patents due to the place of invention, field of technology, or whether imported or locally produced is subject to the non-discrimination clause of Article 27.1. Therefore, a violation of the non-discrimination clause would be a limitation on availability and an encroachment on a State’s obligations under the TRIPs Agreement.<sup>138</sup>

Thus, “Article 27.1 prohibits discrimination as to enjoyment of ‘patent rights’ without qualifying that term.”<sup>139</sup> This includes discriminatory exceptions that block the enjoyment of patents as much as the basic rights themselves.<sup>140</sup> “In the [*Canada—Generic Medicines*] Panel’s view, what was important was that in the rights available under national law, that is to say those resulting from the basic rights and any permissible exceptions to them, the forms of discrimination referred to in Article 27.1 should not be present.”<sup>141</sup> This language was most likely included because the authors of the TRIPs Agreement found it necessary to “require governments to apply exceptions in a non-discriminatory manner, in order to ensure that governments do not succumb to domestic pressures to limit exceptions to areas where right holders tend to be foreign producers.”<sup>142</sup> After all, two primary purposes of Article 27.1 “were to eliminate two types of discrimination that had been practised against pharmaceuticals and certain other products—either a denial of patentability for such products, or, if patents were granted, automatic compulsory licences permitting others to manufacture such products for a fee.”<sup>143</sup> Pharmaceuticals provide an excellent example of these interests

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136. TRIPs Agreement, *supra* note 1, art. 27.1; *Canada—Generic Medicines*, *supra* note 13, ¶ 7.92; TRIPs Facts Sheet, *supra* note 4.

137. TRIPs Agreement, *supra* note 1, art. 27.1 (emphasis added). The clause contains six separate requirements that a country must satisfy to fulfill the non-discrimination requirement because not only must the patent rights be enjoyable “without discrimination as to (1) “place of invention,” (2) “field of technology” and (3) “whether products are imported or locally produced,” but the conjunction “and” denotes that patents must be “available” without discrimination as to those three elements as well.

138. *Id.*

139. *Canada—Generic Medicines*, *supra* note 13, ¶ 7.91.

140. *Id.*

141. *Id.*

142. *Id.* ¶ 7.92.

143. See *id.* ¶ 7.90. The Panel suggests that the implementation of the non-discrimination clause was needed to stop abuses of the system that were going unchecked. In

because patent holders tend to live in developed countries,<sup>144</sup> while those who most need a less costly replica of the patented product live in the developing world.<sup>145</sup> The developing Members do not have a strong research and development base compared to that of developed countries so, in a vast majority of cases they are unlikely to have the ability to develop their own medicines.<sup>146</sup> Therefore, the non-developed countries establish a weak intellectual property legal system and begin copying a product at the expense of a foreign company<sup>147</sup> through denying patentability and granting automatic compulsory licenses.<sup>148</sup>

As discussed earlier, the Panel in *Canada—Generic Medicines* explored the meaning of Article 27's non-discrimination requirement for the field of technology and found that the legal scope and adverse effects of Section 55.2(1) were not limited to the pharmaceutical industry and the government's purpose of Section 55.2(1) was not to specifically disadvantage the pharmaceutical industry, but that Section 55.2(1) applied to all products.<sup>149</sup> The Panel concluded that the EC's claims of discrimination did not have merit because the EC "had not presented sufficient evidence to raise the issue in the face of Canada's formal declaration that the exception of Section 55.2(1) was not limited to pharmaceutical products."<sup>150</sup> With the combination of the statute's text and Canada's assurances that the exception applied to every product subject to regula-

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order to stymie abuses that could potentially now be carried out in the name of the compulsory licenses exception under Article 31 and limited exceptions under Article 30, the Panel found that the non-discrimination requirement applied to both.

144. Nabila Ansari, *International Patent Rights in a Post-Doha World*, 11 CURRENTS: INT'L TRADE L.J. 57, 57 (2002). Ninety-four percent of patents granted world wide and ninety-one percent of cross-border royalties and technology licenses go to the top ten industrialized countries.

145. Bender, *supra* note 6, at 311–12. HIV/AIDS alone affects millions of people in non-developed States, and less expensive drug prices could save thousands of lives every year.

146. Ansari, *supra* note 144, at 57. Developing countries only account for four percent of world research and development figures.

147. Christopher K. Eppich, *Patenting Dilemma: Drugs for Profit Versus Drugs for Health*, 43 SANTA CLARA L. REV. 289, 299–301 (2002). The Pharmaceutical Research and Manufacturers of America reported that it takes twelve to fifteen years to develop a new drug at a cost of \$500 million. Research and development has yielded roughly fifty percent of all new commercial pharmaceuticals worldwide in the last twenty years and exportation comprises around forty percent of industry-wide sales for the US pharmaceutical industry. The lack of IPRs in developing countries leads to a \$5 billion loss annually, of which an estimated \$900 million would have been available for research and development.

148. Ansari, *supra* note 144, at 57. This scenario illustrates the issue at the center of the TRIPs debate: The purpose of TRIPs 27.1, as discussed above, was to make patents available and patent rights enjoyable without discrimination and even though the system may secure those wishes, one may ask whether this Agreement does so at the expense of the people in developing countries.

149. *Canada—Generic Medicines*, *supra* note 13, ¶ 7.105.

150. *Id.* ¶ 7.99.

tory approval the EC needed to provide convincing contrary evidence and it did not.<sup>151</sup> This means that the Panel is willing to accept a State's explanation as to the meaning of the law at issue in determining whether the State conformed to its TRIPs obligations and is willing to do so unless it has sufficient reason to doubt the truthfulness of the State's representations.<sup>152</sup> The Panel's decision, however, challenges States to fashion their policies in a way that more closely complies with the purposes of TRIPs, making it harder for States to abuse loopholes.<sup>153</sup>

### B. Articles 28 and 30: An Unbreakable Link

While Article 27 mandates the availability of patents and enjoyment of patent rights without discrimination, Article 28: Rights Conferred actually confers the rights granted to a patent holder.<sup>154</sup> Article 28 gives the patent owner the "exclusive rights" "to prevent third parties not having the owners consent from the acts of: making, using, offering for sale, selling, or importing" the product, the process, and the product from the process protected under the patent.<sup>155</sup> The patent owner may also assign, transfer by succession, and license the patent to third parties.<sup>156</sup> The only express limitation upon Article 28 within its text is in a footnote that subjects it to Article 6 which is not applicable to this discussion.<sup>157</sup> Taking the text of Articles 28.1 and 33 on their ordinary meaning, it would seem the exclusive rights of patents conferred in Article 28.1 cannot be infringed upon (minus the exceptions later discussed) for at least twenty years from the original grant or filing date of original grant.<sup>158</sup> Hence, any law allowing the making, using, offering for sale, selling, or importing of a product without the patent holders permission is a violation of Article 28 unless an exception for such action is provided under Article 30 or 31.<sup>159</sup>

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151. *Id.*

152. *See id.*

153. *Id.* ¶ 7.94.

154. TRIPs Agreement, *supra* note 1, arts. 27–28; Champ & Attaran, *supra* note 9, at 382–83. Hence, Article 27 establishes the basic standard that States must adopt within their patent system, but it does not grant any express rights for a patent holder.

155. TRIPs Agreement, *supra* note 1, art. 28.1(a); Cynthia M. Ho, *Patents, Patients, and Public Policy: An Incomplete Intersection at 35 U.S.C. § 287(c)*, 33 U.C. DAVIS L. REV. 601, 655 (2000). "Article 28 thus provides that an owner of a patented process shall have an exclusive right to prevent all others from using the patented process."

156. TRIPs Agreement, *supra* note 1, art. 28.2.

157. *Id.* arts. 6, 28 n.7. "This right, like all others conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6."

158. *Id.* arts. 28, 33.

159. *Id.* arts. 28, 30, 31; Canada—Generic Medicines, *supra* note 13, ¶ 7.18.



Understandably, one limitation on Article 28 is the applicability of Article 27.1 because if a country rightfully exercises one of its exceptions to patentability under Article 27, the innovator does not have the ability to patent its innovation, and, therefore, no rights would be conferred.<sup>160</sup> Another limitation on the rights in Article 28 is under Article 32 where a company can have its patent revoked or forfeited if judicial review finds such action appropriate.<sup>161</sup>

The exclusive use protected by Article 28 has two other exceptions that may be used in limited circumstances: Articles 30 and 31.<sup>162</sup> Article 30: Exceptions to Rights Conferred states:

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.<sup>163</sup>

The link between Articles 28 and 30 rests on the words "limited exceptions to the exclusive rights conferred."<sup>164</sup> Article 28 utilizes the phrase "exclusive rights" to describe the rights a patent confers unto its owner and Article 30 contains language that allows States to "provide limited exceptions to the *exclusive rights* conferred by a patent."<sup>165</sup> Article 27 does not grant any exclusive rights, however; it establishes that a government must make patents available and patent rights enjoyable without discrimination, as long as the item meets all the requirements of the Article and is not subject to one of the internal limitations.<sup>166</sup> As a matter of fact, the internal limitations within Article 27.1 are all exclusions to the actual patentability of the items affected and do not even address what rights a patent holder possesses.<sup>167</sup> The limitations, just as Article 27.1 as a whole,

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160. TRIPs Agreement, *supra* note 1, arts. 27–28.

161. *Id.* arts. 28, 32.

162. *Id.* arts. 30, 31. The compulsory licenses of Article 31 are a popular method to avoid the rights conferred under Article 28, but will only be addressed in a limited capacity here.

163. *Id.* art. 30.

164. *Id.* arts. 28, 30.

165. *Id.*

166. *Id.* art. 27. The term "internal limitations" is a reference to the provisions and articles that sentences one and two of Article 27.1 are subject to. Although Article 27 does not use the term "exclusive," it reinforces Article 28's concept of exclusivity by stating that "patent rights [shall be] enjoyable without discrimination."

167. *Id.* arts. 27.1–27.3, 65.4, 70.8. Article 27.3 in its pertinent part, describes "what members may exclude from patentability." Article 65.4 allows a state to extend the introduction of patent protection for items "not so protectable in its territory." Article 70.8 addresses the steps a state must take to protect pharmaceuticals and agricultural chemical products when

merely describe when a State must make patents available and patent rights enjoyable without discrimination.<sup>168</sup> Minus an express link such as between Articles 28 and 30, one may question whether the limitations of Article 30 should apply to Article 27.1.<sup>169</sup> “Because the fundamental principle behind the patent provisions is to provide exclusive rights, allowing article 30 to provide an exception for all activity would be improper.”<sup>170</sup>

Returning back to a pure discussion of Article 30, this Article:

Establishes three criteria that must be met in order to qualify for an exception: (1) the exception must be “limited”; (2) the exception must not “unreasonably conflict with normal exploitation of the patent”; (3) the exception must not “unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”<sup>171</sup>

These three tests or “conditions” are cumulative in nature which means each is “a separate and independent requirement that must be satisfied.”<sup>172</sup> “Failure to comply with any one of the three conditions results in the Article 30 exception being disallowed.”<sup>173</sup> When interpreting the conditions, they must be “interpreted in relation to each other” and each “must be presumed to mean something different from the other two, or else there would be redundancy.”<sup>174</sup> Even though an exception may be “limited” under the first condition, it can still violate the second and third; likewise, if the exception is both limited and does not “unreasonably conflict with a normal exploitation” it could still violate test three

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it does not make those patents available on the Agreement’s date of entry into force. Ho, *supra* note 155, at 658–59. “Interpreting the patent enforcement right requirement in view of the patentability exceptions of article 27 is inappropriate, as article 27’s exceptions expressly pertain to patentability, not enforceability.”

168. *Id.*

169. Ho, *supra* note 155, at 661. “The article cannot be reasonably interpreted to swallow entirely the substantive patent provisions of TRIPS. Panel decisions . . . have reinforced the idea that exceptions are intended to be just that—exceptions that do not emasculate the general principles established in the agreements.” See Robert Weissman, *A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT’L ECON. L. 1069, 1108 (1996), *reprinted in Special Series: The Journey in Review: A Look Back at Twenty-Five Years of the University of Pennsylvania Journal of International Economic Law*, 25 U. PA. INT’L BUS. L. 1079 (2004). “Although Article 30 does not condition exceptions on national purpose, it does impose conditions on the right to make exceptions to the overall Agreement. These conditions are logical, because there is no evidence that Article 30 was intended as an all-purpose opt-out from TRIPs patent rules.” *Id.*

170. Ho, *supra* note 155, at 661.

171. Canada—Generic Medicines, *supra* note 13, ¶ 7.20.

172. *Id.*

173. *Id.*

174. *Id.* ¶ 7.21.

and "unreasonably prejudice the legitimate interests of the patent owner."<sup>175</sup>

Test one dictates that any exception to Article 28 must be "limited."<sup>176</sup> The Panel in *Canada—Generic Medicines* agreed with the EC's assertion that the word "limited" meant "narrow, small, minor, insignificant or restricted"<sup>177</sup> rather than the broader definition of "confined within definite limits," or "restricted in scope, extent, amount" presented by Canada.<sup>178</sup> Whether an exception is "limited" is not just a determination as to how many of the five rights granted by Article 28 were impaired, but a measure as to the extent each patent owner's rights were infringed.<sup>179</sup> At the same time, a "limited" exception is not one that just preserves a single right such as selling because each right was included in TRIPs so they are all "meaningful and independent part[s] of the patent owner's rights."<sup>180</sup>

The first balancing test within Article 30 lies within the second criteria: "such exceptions do not unreasonably conflict with a normal exploitation of the patent."<sup>181</sup> Two main questions arise from this test: (1) what is a "normal exploitation" and (2) what is an "unreasonabl[e] conflict."<sup>182</sup>

"Normal exploitation" is the "regular, usual, typical, ordinary, [or] conventional"<sup>183</sup> "commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent."<sup>184</sup> In explaining this definition, the Panel opined: "The normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity."<sup>185</sup> As applied to *Canada—Generic*

175. TRIPs Agreement, *supra* note 1, art. 30; *Canada—Generic Medicines*, *supra* note 13, ¶ 7.21.

176. TRIPs Agreement, *supra* note 1, art. 30; *Canada—Generic Medicines*, *supra* note 13, ¶ 7.20.

177. *Canada—Generic Medicines*, *supra* note 13, ¶ 7.28. A standard as lax as the Canadian proposal which follows could seemingly open up many more loopholes to the agreement than originally planned by defining the term so broadly.

178. *Id.* ¶ 7.27.

179. *Id.* ¶ 7.32. The five rights referred to in this sentence are the "making, using, offering for sale, selling, or importing" provided for in Article 28. The Panel made perfectly clear that the standard was not how many rights were violated, but to what extent they were violated: "A very small act could well violate all five rights provided by Article 28.1 and yet leave each of the patent owner's rights intact for all useful purposes."

180. *Id.*

181. TRIPs Agreement, *supra* note 1, art. 30.

182. *Id.*

183. *Canada—Generic Medicines*, *supra* note 13, ¶ 7.54.

184. *Id.*

185. *Id.* ¶ 7.55.

*Medicines*, the Panel disagreed with Canada's assessment that "normal exploitation" did not include the years immediately after the term of protection because some patent rights "will typically produce a certain period of market exclusivity after the expiration of a patent."<sup>186</sup> After all, the Panel believed that a truly effective use of patent rights depended on the circumstances of the individual product markets and standards.<sup>187</sup> An example justifying this line of reason is the right to prevent the "making" of patented products during the patent term.<sup>188</sup> If TRIPs guarantees that other actors cannot make the patented product for the entire twenty years of market exclusivity, then naturally there will be a layover period immediately following the patent term until a market competitor can "make" enough copied products to vigorously compete in the open market.<sup>189</sup> The Panel agreed, however, with Canada's general proposition that the "defacto market exclusivity" created by the patent rights does not preclude Canada from allowing the regulatory review process to proceed during the patent term.<sup>190</sup> The extended market exclusivity is not guaranteed as a "natural exploitation" of patent rights, but is an unintended process of the patent rights and regulatory rules not overlapping properly.<sup>191</sup> The Panel quickly qualified its acceptance of the Canadian exception under test two by saying that the regulatory process caused the overlap and that most products do not have to worry about such a problem.<sup>192</sup> This explanation probably means that the Panel saw the circumstances caused by the regulatory process as unique and a limited reason to allow for the Canadian exception since the very nature of the products is what caused the de facto extension of market exclusivity.<sup>193</sup>

The definition of "unreasonably" within this test was not explored by the Panel, but in ordinary terms means "not reasonable; immoderate; exorbitant."<sup>194</sup> The word reasonable means "suitable under the

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186. *Id.* ¶ 7.56.

187. *Id.* ¶ 7.55. The Panel felt that the application of patent rights had to change depending on technological developments and effective marketing practices. Patents create a period of market exclusivity as an incentive for innovation of new products and the owners of patents, as part of their reward for the investment in innovation, should be able to take "effective advantage" of their patents—even if this market exclusivity reaches beyond the 20 year patent term mandated in TRIPs.

188. *Id.* ¶ 7.56.

189. *Id.*

190. *Id.* ¶ 7.57

191. *Id.*

192. *Id.*

193. *See id.* The Panel's language seems to limit the application of such an exception because it stresses how this extension is not "natural or normal," "an unintended consequence," and for most products does not apply because there is no "marketing approval process for competitors."

194. Black's Law Dictionary 1538 (6th Ed. 1990).

circumstances” and “fit and appropriate to the end in view.”<sup>195</sup> In other words, if the action is a normal exploitation of patent rights and a country’s regulatory rules conflict with the exploitation, the conflict must be “fit and appropriate” under the object and purposes of the treaty to avoid an encroachment of the rights granted by TRIPs.<sup>196</sup>

The final test in Article 30 is that an exception cannot “unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”<sup>197</sup> This clause also demands a balancing test, broken down into four considerations: (1) what are “legitimate interests of the patent owner”; (2) does the exception unreasonably prejudice those legitimate interests; (3) what are the legitimate interests of third parties and; (4) considering the third party’s legitimate interests, does the exception unreasonably prejudice the legitimate interests of patent owners.<sup>198</sup> Similarly to the second condition of Article 30, this test also asks whether it is acceptable to remove the additional period of market exclusivity by having such an exception.<sup>199</sup> In arguing the definition of “legitimate interests,” the EC claimed that “legitimate interests” were essentially the legal rights of the patent holder and the third parties and since the legal rights of the patent owner prescribed under Article 28 were for exclusive making, using, and selling of the product or process by the owner, only the patent owner could engage in Article 28 actions during the patent term.<sup>200</sup> This definition created an even more favorable standard for the EC when combined with their extremely narrow definition of “third parties” which the EC defined not as other countries, but competitor drug companies.<sup>201</sup> Correspondingly, as competitor drug companies held no legal right to the production, use, or sale of the products or processes during the patent term, they have no legitimate interest in the exception.<sup>202</sup> The Panel dismissed this circular

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195. *Id.* at 1265.

196. TRIPs Agreement, *supra* note 1, art. 30; Canada—Generic Medicines, *supra* note 13, ¶¶ 7.20–7.22. Both the EC and Canada argued that Articles 7 and 8 were important to understanding the true meaning of Article 30 and its application under these circumstances. *Id.* ¶ 7.23.

197. TRIPs Agreement, *supra* note 1, art. 30; Canada—Generic Medicines, *supra* note 13, ¶ 7.60.

198. TRIPs Agreement, *supra* note 1, art. 30.

199. Canada—Generic Medicines, *supra* note 13, ¶ 7.61. This test, much like the second condition, boils down to two questions—(1) does Canada have a legitimate interest in this exception and (2) does the exception unreasonably prejudice the patent holder?

200. *Id.* ¶¶ 7.62–7.63.

201. *Id.* ¶ 7.62. The EC claims that competitor drug companies are the only applicable third parties because they are the “only parties with interests adverse to those of patent owners.”

202. *Id.* ¶¶ 7.63–7.64. The competitor companies held no legal right because the text of the treaty demands that twenty years be the applicable patent term. Interestingly, the EC argued that the rights and interests granted under TRIPs cannot conflict with social welfare

definition stating that "legitimate interests" were not just legal rights, but "a normative claim calling for protection of interests that are 'justifiable' in the sense that they are supported by relevant public policies or other social norms."<sup>203</sup> This definition considers interests outside of the economic world of the pharmaceutical industry and examines what society may see as "legitimate interests."<sup>204</sup> After all, a definition that rests solely on legal rights would make the rest of Article 30 redundant.<sup>205</sup> The Panel did not directly define "third parties," but in its rejection of the EC's narrow legal rights argument and emphasis on public policies, one could believe that relevant third parties include governments.<sup>206</sup> After all, the Panel earlier recognized Canada's interest in ensuring that products that have to go through a strict regulatory process are market ready by the end of the patent term through the use of such exceptions.<sup>207</sup> Additionally the Panel rejected the EC's argument that since they have to satisfy the regulatory process during the patent term this shortens their market exclusivity and the *de facto* extension after the twenty year term helps alleviate this burden.<sup>208</sup> Such a burden was not found compelling enough to justify a finding against Canada because the actual legitimacy of such an interest was still being debated in the WTO community and it is not the role of adjudication to make such a decision.<sup>209</sup>

## VI. A HUMBLE INTERPRETATION OF THE INTERACTION BETWEEN ARTICLES 27, 28, AND 30

As previously stated, to truly understand the meaning and interaction of the Articles, one must study the treaty as a whole.<sup>210</sup> Outside of Section 5 are four provisions that help guide the overall understanding and meaning of the TRIPs Agreement: Article 3; National Treatment; Article 4; Most-Favoured-Nation Treatment; Article 7 Objectives; and Article 8

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policy. However, the EC established this claim within the context that the general welfare demands protection of the full patent term. One may question whether the general welfare that this exception is guaranteed to protect involves the social welfare via patent rights, or social welfare via decreased pharmaceutical costs at the expiration of the patent term.

203. *Id.* ¶ 7.69. This interpretation of "legitimate interests" is also supported by Article 9(2) of the Berne Convention from which this element is taken verbatim.

204. *Id.*

205. *Id.* ¶ 7.68.

206. *Id.* ¶¶ 7.68–7.69, ¶ 7.73.

207. *Id.* ¶¶ 7.54–7.59.

208. *Id.* ¶¶ 7.82–7.83. Interestingly, the Panel says that a number of countries agreed with the EC's claim that companies affected by the regulatory process deserve the *de facto* extension, even some countries going as far as to grant compensatory patent term extensions.

209. *Id.* The Panel believed this is a normative policy issue that is still a matter of unresolved political debate.

210. Champ & Attaran, *supra* note 9, at 383.

Principles. Articles 3 and 4 establish the minimum non-discrimination standards of the TRIPs Agreement,<sup>211</sup> whereas Articles 7 and 8 are an internal interpretative authority that must be used whenever analyzing the meaning of distinct provisions.<sup>212</sup> The meaning of these provisions as laid out below will guide the discussion of the articles' interaction.

Before moving to the articles mentioned above, one must also briefly establish the other basic interpretation tools provided for in TRIPs. Article 1: Nature and Scope of Obligations and Article 2: Intellectual Property Conventions both guarantee that the rights and obligations of the Paris Convention, Berne Convention, Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits shall be enforced in addition to the express language within TRIPs—with the TRIPs Agreement overriding any conflict.<sup>213</sup> Additionally, under Article 5: Multilateral Agreements on Acquisition or Maintenance of Protection, the obligations under Articles 3 and 4 do not apply to agreements under WIPO “relating to the acquisition or maintenance of intellectual property rights.”<sup>214</sup> Therefore in determining a Member State's obligations under TRIPs, the evaluator must look at the text of the TRIPs Agreement itself as well as the responsibilities under other intellectual property agreements.<sup>215</sup>

#### *A. National Treatment and Most Favoured Nation Status, TRIPs Style*

Two cornerstones of the world trading system are national treatment and most favoured nation status (MFN).<sup>216</sup> The first case to address both MFN and national treatment under the TRIPs Agreement was *United States—Section 211 Omnibus Appropriations Act of 1998 (Havana Club)* which involved Sections 211(a)(2) and (b) of the Omnibus Appropriations Act.<sup>217</sup> The Omnibus Act discussed the treatment of trademarks that had been confiscated by the Cuban government after the communists came to power.<sup>218</sup> The EC contended that discriminatory treatment was extended to “successors-in-interest” and “original owners” of confis-

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211. United States—Section 211 Omnibus Appropriations Act of 1998 (Havana Club), Jan. 2, 2002, DSR 2002: II 589, WTO Doc. WT/DS176/AB/R.

212. Canada—Generic Medicines, *supra* note 13, ¶ 7.26.

213. TRIPs Agreement, *supra* note 1, arts. 1–2.

214. *Id.* art. 5.

215. *Id.* arts. 1–5.

216. Havana Club, *supra* note 211, P 241, 297. Both obligations are essential to 1994 GATT, and at the Uruguay Round, the WTO inserted these provisions into the TRIPs Agreement.

217. *Id.* § IIA.

218. *Id.* ¶ 4. “Havana Club” was a trademark confiscated by the Cuban government from an American company and sold to a European company.

cated trademarks who were foreign nationals.<sup>219</sup> The Appellate Body found the United States had violated its national treatment obligations under Article 3.1 TRIPs by discriminating against non-U.S. nationals who were successors in interest under Section 211(a)(2) and discriminating against non-U.S. nationals who were original owners under Section 211(a)(2) and (b).<sup>220</sup> Additionally, the Appellate Body found that the United States had violated its MFN obligations under Article 4 TRIPs by affording better treatment to “non-Cuban foreign nationals” than Cuban nationals.<sup>221</sup>

### 1. National Treatment

The Appellate Body explained that “[t]he national treatment obligation is a fundamental principle underlying the *TRIPS Agreement*, just as it has been in what is now the GATT 1994.”<sup>222</sup> It further stated: “As articulated in Article 3.1 of the *TRIPS Agreement*, the national treatment principle calls on WTO Members to accord no less favourable treatment to non-nationals than to nationals in the ‘protection’ of trade-related intellectual property rights”<sup>223</sup> and this protection extends to “matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights specifically addressed in this [TRIPs] Agreement.”<sup>224</sup>

An additional aspect to the TRIPs national treatment provision is its unique phrase “only where such exceptions are necessary to secure compliance with laws and regulations which are not inconsistent with the provisions of this Agreement and where such practices are not applied in

219. *Id.* ¶¶ 43–47.

220. *Id.* ¶¶ 268, 281. The provision says a US court cannot “recognize, enforce, or otherwise validate any assertion of rights by a ‘designated national’ that claims its interest from the confiscated property.” *Id.* ¶ 247. The Appellate Body explained that “even the possibility that non-United States successors-in-interest face two hurdles is *inherently less favourable* than the undisputed fact that United States successors-in-interest face only one.” *Id.* ¶ 265.

221. *Id.* ¶ 319. The EC alleged a MFN violation against the United States for granting “non-Cuban foreign nationals” preferential treatment as compared to Cuban nationals saying that Sections 211(a)(2) and (b) were *prima facie* discriminatory against Cuban nationals because the words “designated national” within the section only applied to original owners who were Cuban nationals. *Id.* ¶¶ 307–09. The Appellate Body agreed—stating that Cuban nationals who reside in the “authorized trade territory” face an additional administrative procedure that does not apply to non-Cuban foreign nationals who are original owners, because the latter are not “designated nationals.” *Id.* ¶ 314.

222. *Id.* ¶ 242. The Appellate Body emphasizes the absolute importance of this provision and how its additional inclusion in the TRIPs Agreement even after its inclusion in GATT 1994 and the Paris Convention both of which are interpretive tools of TRIPs, shows how important the TRIPs negotiators found the provision.

223. *Id.* ¶ 243.

224. TRIPs Agreement, *supra* note 1, art. 3 n.3.



a manner which would constitute a disguised restriction on trade.”<sup>225</sup> Such a phrase is not found in the GATT Article III, but comparable language, “disguised restriction on trade,” is present in the chapeau of Article XX GATT which restricts “exceptions to substantive obligations” of the GATT including national treatment if the “measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade.”<sup>226</sup> Looking at the interpretations of similar GATT provisions is useful in determining the meaning of the disguised restriction clause because the clause is a limitation upon the substantive exceptions to national treatment under GATT just as it is a limitation on the substantive exceptions to national treatment under TRIPs.<sup>227</sup> Following the GATT standard, a disguised restriction on trade under TRIPs is any constraint that meets the requirements of an exception under TRIPs, but is actually a “disguise to conceal the pursuit of trade-restrictive objectives.”<sup>228</sup> Therefore, an exception to Article 3 TRIPs would not be available to a Member State who tried to disguise a trade restrictive objective through a seemingly valid exception.

## 2. Most Favoured Nation Status

Just as the Appellate Body accorded great respect to the national treatment provisions of TRIPs, it placed great importance upon MFN as well: “As a cornerstone of the world trading system, the most-favoured-nation obligation must be accorded the same significance with respect to intellectual property rights under the *TRIPS Agreement* that it has long been accorded with respect to trade in goods under the GATT. It is, in a word, fundamental.”<sup>229</sup> MFN treatment in Article 4 guarantees for intellectual property rights that “any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other

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225. *Id.* art. 3.

226. General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194, art. III, XX; US—Importation of Certain Shrimp and Shrimp Products (United States—Shrimp), May, 15, 1998, DSR 1998: VII 2755, WTO Doc. WT/DS58/AB/R (explaining the meaning of Article XX).

227. See TRIPs Agreement, *supra* note 1, art. 3; GATT, *supra* note 226, art. XX. Such an exercise is valid because when interpreting Articles 3 and 4 in Havana Club the Appellate Body compared TRIPs and GATT provisions as two foundations of international trade. Havana Club, *supra* note 211, ¶¶ 242, 297.

228. European Communities—Measures Affecting Asbestos and Asbestos-Containing Products (EC—Asbestos), Sept. 18, 2000, DSR 2001: VIII 3305, WTO Doc. WT/DS135/R P 8.236.

229. Havana Club, *supra* note 211, ¶ 297.

Members.”<sup>230</sup> Article 4 does contain four exceptions including agreements on intellectual property that were “entered into force prior to the entry into force of the WTO Agreement,” if the Council for TRIPs was notified of those agreements and the agreements “do not constitute an arbitrary or unjustifiable discrimination against nationals of other members.”<sup>231</sup> To ensure that a provision does not infringe upon national treatment or MFN obligations, the legislation cannot be *prima facie* discriminatory.<sup>232</sup> If it is *prima facie* discriminatory, the Member must show that enforcement of the provision would not lead to discriminatory treatment under any circumstances.<sup>233</sup>

### B. Objectives and Principles of TRIPs

Articles 7 and 8 establish the foundation for determining whether a State action helps further the purposes of the TRIPs Agreement.<sup>234</sup>

Article 7: Objectives states:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.<sup>235</sup>

Article 8: Principles provides:

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

230. TRIPs Agreement, *supra* note 1, art. 4.

231. *Id.* Therefore, aside from the obligations to other treaties established in Articles 1 and 2, MFN expressly contains language that demands the reference to other agreements in determining MFN duties.

232. Havana Club, *supra* note 211, ¶¶ 307–09, 317–18.

233. *See id.* ¶¶ 282–82, 310–11.

234. Canada—Generic Medicines, *supra* note 13, ¶ 7.26; Wesley A. Cann Jr., *On the Relationship Between Intellectual Property Rights and the Need of Less-Developed Countries for Access to Pharmaceuticals: Creating a Legal Duty to Supply Under a Theory of Progressive Global Constitutionalism*, 25 U. PA. J. INT’L BUS. L. 755, 806–07 (2004). “The Declaration on TRIPS also recognized that each provision of the TRIPS Agreement must be interpreted in light of the Agreement’s objectives and principles as is mandated by Article 31 of the Vienna Convention on the Law of Treaties.”

235. TRIPs Agreement, *supra* note 1, art. 7.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.<sup>236</sup>

A careful balance must be sought between what some countries would argue is a legitimate use of Articles 7 and 8 to further a Member's socio-economic policies while others would say that using the provisions in Articles 7 and 8 too aggressively would amount to a renegotiation of the TRIPs Agreement.<sup>237</sup> The text recognizes the importance of technological innovation and the dissemination of that technology, and wants the innovation and dissemination to be mutually advantageous to users and producers.<sup>238</sup> An example of such an arrangement is that Company A sells a new pharmaceutical at a reasonable price to cover its costs and create profits while Country B's population can readily consume said pharmaceuticals, alleviating a public health concern. Both actors benefited from the innovation and transfer because Company A recovered its costs and made profits on the drug, the innovation and dissemination of which were driven by the demand in Country B, and Country B benefited from the innovation and dissemination because the new drug cured a public health crisis. The second part of Article 7 adds an additional dimension to the objectives: the protection and enforcement of intellectual property rights must be "conducive to social and economic welfare."<sup>239</sup> Hence, "Article 7 speaks in terms of protecting intellectual property in a way that creates a 'mutual advantage' for producers and consumers, that establishes a 'balance of rights and obligations' and that is applied 'in a manner conducive to social and economic welfare.'"<sup>240</sup>

As argued in *Canada—Generic Medicines*, the social and economic welfare of a State can be very different than the potential patent rights of a company—the EC companies stood to lose C\$100 million per year

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236. *Id.* art. 8.

237. *Canada—Generic Medicines*, *supra* note 13, ¶¶ 7.24–7.25. Canada argued that Articles 7 and 8 ensure that States can balance their socio-economic interests against the patent rights created by TRIPs. This means that Canada's exceptions should be allowed because TRIPs demands that governments have the "necessary flexibility to adjust patent rights to maintain the desired balance with other important national policies." The EC criticized this view as being too broad because even though the articles allow for the balance between patent rights and governmental policies, Canada's interpretation would amount to a renegotiation of TRIPs. The EC also pointed to Article 8.1 to explain that even though States can balance their TRIPs obligations against their socio-economic policies, Member States must do so in a way that is consistent with their TRIPs obligations.

238. TRIPs Agreement, *supra* note 1, art. 7.

239. *Id.*

240. *Cann*, *supra* note 234, at 807.

from the Canadian exceptions, but at the same time, Canada had a recognized interest of wanting to keep its citizens' health care costs to a minimum.<sup>241</sup> Thus, "all provisions of the TRIPS Agreement must be viewed in terms of a bargained-for exchange, and the protection of intellectual property must be seen not merely as a static set of rules, but as a mandated 'process' ultimately leading to a series of mandated benefits."<sup>242</sup>

Article 8: Principles seemingly lends more guidance for the objectives in Article 7 by providing for the promotion of "the public interest in sectors of vital importance to their [the country in question] socio-economic and technological development" and expressly listing "measures necessary to protect public health and nutrition" as items a country can consider when "formulating or amending their laws and regulations" to comply with TRIPs.<sup>243</sup> Also allowable under Article 8.2 are "appropriate measures" to prevent IPRs owners from: (1) abusing their rights; (2) using practices that "unreasonably restrain trade"; or (3) "adversely affect the international transfer of technology."<sup>244</sup> The phrase "provided that such measures are consistent with the provisions of this Agreement," however, creates a circular line of reasoning that some people have argued limits these principles to determinations that a questionable action is within the rights granted by the Agreement.<sup>245</sup>

Although Article 8 seems to provide substantial latitude to Member States in applying exceptions for public health,<sup>246</sup> the leeway is not unlimited.<sup>247</sup> Members may take measures to prevent "abuse" of IPRs, but these procedures must remain consistent with the TRIPs Agreement.<sup>248</sup> Secondly, in using the term "necessary," Article 8 seems to "indicate that the imposition of these measures are not within the absolute discretion of the invoking Member, but are instead subject to potential WTO review in regard to their validity."<sup>249</sup> Finally, "the phrase 'provided that such measures are consistent with the provisions of the Agreement' is substantially more restrictive than the "General Exceptions" found in Article XX of the [GATT] 1994, which allows measures

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241. Canada—Generic Medicines, *supra* note 13, ¶¶ 7.24–7.25.

242. Cann, *supra* note 234, at 808.

243. TRIPs Agreement, *supra* note 1, art. 8.

244. *Id.*

245. Canada—Generic Medicines, *supra* note 13, ¶¶ 7.24–7.25.

246. Cann, *supra* note 234, at 808–09.

247. *Id.*

248. *Id.* at 809.

249. *Id.* at 808. Comparatively, this wording seems stricter than the security exception in Article 73 which provides a Member State much more freedom by placing a subjective standard ("it considers necessary").

that would otherwise be inconsistent with the GATT Agreement.”<sup>250</sup> Article 8 is not an exception to TRIPs, but “a guiding principle upon which all other provisions of the Agreement must be read.”<sup>251</sup>

Although the Panel in *Canada—Generic Medicines* did not directly define or limit Articles 7 or 8, one may imply some explanations from its judgment. First, the Panel said when determining whether an exception falls within Article 30, one must use Articles 7 and 8 to fully understand the applicable texts and ensure that any interpretation furthers the objects and purposes of the Agreement.<sup>252</sup> Thus, the Panel must have felt that Canada’s regulatory review exception in Section 55.2(1) was valid under the objects and purposes of TRIPs because it deemed the exception valid.<sup>253</sup> This means that in certain circumstances when regulatory review of a product is mandated by a government before the product is released on the market, a government could allow for an imitative product to begin the review process before the initial twenty year patent term expires.<sup>254</sup> Correspondingly, Canada’s “stockpiling exception” in Section 55.2(2) deemed invalid under Article 28 cannot be within the objects and purposes of TRIPs, meaning that under Article 30 a State will need a greater social or economic interest than ensuring lower priced medicines immediately upon the expiration of the patent term for its exception to fall within the objects and purposes of TRIPs.<sup>255</sup> The Panel, however, was inconsistent in its analysis of the de facto patent term extension—saying “it must be recognized that enforcement of the right to exclude ‘making’ and ‘using’ during the patent term will necessarily give all patent owners, for all products, a short period of extended market exclusivity after the patent expires”<sup>256</sup> when discussing the “stockpiling exception,” but declaring “the additional period of market exclusivity in this situation is not a natural or normal consequence of enforcing patent rights. It is an unintended consequence of the conjunction of the patent laws with product regulatory laws” while talking about the regulatory review exception.<sup>257</sup> Despite this unpredictability, it seems that Articles 7 and 8

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250. *Id.* at 808–09.

251. *Id.* at 809.

252. *Canada—Generic Medicines*, *supra* note 13, ¶ 7.26.

253. *See id.* After all, by default, if such an exception were not acceptable under the object and purposes of TRIPs it cannot be valid under a more specific provision.

254. *Id.* ¶¶ 7.24–7.25, 7.84, 7.104.

255. *Id.* ¶¶ 7.35–7.38.

256. *Id.*

257. *Id.* ¶ 7.57. This footnote shows the trouble that a State or the DSB can have in maintaining a consistent theory and understanding of the objects and purposes of the TRIPs Agreement and how the same balancing test can lead to such different conclusions on the same issue. Such inconsistency makes it difficult for States to predict a potential judgment by the DSB.

allow for a broad reading of the TRIPs Agreement, especially since the Panel allowed the regulatory review exception that so blatantly violated Article 28.1. Some scholars have interpreted the text of Articles 7 and 8 very broadly following *Canada—Generic Medicines*, with two scholars arguing that “it would be a poor lawyer indeed or a particularly malevolent government that could not devise a TRIPs consistent way to accomplish its objectives related to any of those [public health and nutrition] policy areas.”<sup>258</sup>

### C. Articles 27 and 30—an Unequal Duel

When the Panel in *Canada—Generic Medicines* addressed the relationship between Article 27.1 and Articles 30 and 31, it stated that both Articles 30 and 31 were subject to the non-discrimination clause because “Article 27.1 prohibits discrimination as to enjoyment of ‘patent rights’ without qualifying that term.”<sup>259</sup> The Panel further opines: “a discriminatory exception that takes away enjoyment of a patent right is discrimination as much as is discrimination in the basic rights themselves.”<sup>260</sup> Some commentators tend to disagree with this interpretation, however, saying that if Article 27 preempts Articles 30 and 31, this would severely limit the ability of states to use the exceptions provided for in those Articles.<sup>261</sup> In fact, they claim that Articles 27 and 28 are tied together as general propositions within the treaty and that Articles 30 and 31 are specific exceptions to the rights granted by Articles 27 and 28.<sup>262</sup> Developing Members also promoted such an authoritative interpretation of Articles 30 and 31, especially following the Doha Declaration.<sup>263</sup> However, this author respectfully disagrees because “a widespread and factually unlimited authoritative interpretation of Article 30 of the type advocated by the developing countries, would ultimately undermine the social benefits of patent rights.”<sup>264</sup> Such an understanding

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258. Peter N. Fowler & Alice T. Zalik, *A U.S. Government Perspective Concerning the Agreement on the Trade-Related Aspects of Intellectual Property: Past, Present and Near Future*, 17 ST. JOHN'S J. LEGAL COMMENT. 401, 412–13 (2003).

259. *Canada—Generic Medicines*, *supra* note 13, ¶ 7.91.

260. *Id.*

261. Champ & Attaran, *supra* note 9, at 386. These authors write in the content of Brazilian local working permits. The Brazilian law that was meant to bring Brazil into compliance allowed for the Brazilian government to authorize a compulsory license if the “patent owner does not manufacture the product in the territory of Brazil within three years of the patent grant.” The law allowed for exceptions to this rule, but the United States claimed in a Panel complaint which was later settled out of the DSB.

262. *Id.* at 386–90.

263. Thomas A. Haag, *TRIPS Since Doha: How Far Will the WTO GO Toward Modifying the Terms for Compulsory Licensing?*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 945, 957–60 (2002).

264. *Id.* at 965–66.

by Member States would “greatly hamper the ‘dissemination and advancement of technical knowledge’ because it would encourage inventors to maintain their inventions as trade secrets as the only mechanism of protection for their intellectual and financial investments.”<sup>265</sup> This would cause an end result of limiting the dissemination of technology, which is “clearly contrary to the objectives recited in Articles 7 and 8.”<sup>266</sup>

With all the contrasting opinions<sup>267</sup> and interests<sup>268</sup> that lay in this field, one must tread lightly when trying to determine how to interpret Section 5 Patents. Three main themes of the TRIPs negotiations regarding patents were: (1) non-discrimination; (2) terms of patent protection; and (3) compulsory licenses and exceptions.<sup>269</sup> Although the exact non-discrimination clause in the text today did not appear in any of the previous submitted drafts, it has legitimate backing within the negotiations.<sup>270</sup> The United States, Japan, Australia, the EC, New Zealand, Hong Kong, Canada, Brazil, and the Nordic Countries all called for the appearance of national treatment provisions within the TRIPs Agreement and most of these countries called for MFN status as well.<sup>271</sup> Canada, Hong Kong, the Nordic Countries, Australia, and Japan all called for additional non-discriminatory provisions.<sup>272</sup> Some developing countries were concerned that a rigid non-discrimination standard would not allow them to have exceptions for specific sectors such as chemicals, pharmaceuticals, and food stuffs that are necessary for further development, especially since many of the developed countries had just recently added protection for these sectors to their state patent laws.<sup>273</sup>

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265. *Id.* at 966.

266. *Id.*

267. Thomas F. Cotter, *Market Fundamentalism and the TRIPs Agreement*, 22 CARDOZO ARTS & ENT. L.J. 307 (2004); Champ & Attaran, *supra* note 9; Hagg, *supra* note 263; Kiehl, *supra* note 12; Weissman, *supra* note 169.

268. *See supra* Part IV.

269. *See* Negotiating Group on TRIPs, Meeting of Negotiating Group of 11–12 May 1989, Feb. 2, 1990, GATT Doc. MTN.GNG/NG11/W/32/Rev.2, 92–93, 98–103, 106–07 [hereinafter Negotiating Group W32r2].

270. *See* Negotiating Group on TRIPs, Meeting of Negotiating Group of 27 March 1990, Mar. 28, 1990, GATT Doc. MTN.GNG/NG11/W/68; Negotiating Group W32r2 at 86–89, 106–07.

271. Negotiating Group W32r2 at 84–85.

272. *Id.*

273. Negotiating Group on TRIPs, Meeting of Negotiating Group on 2, 4 and 5 April 1990, Apr. 24, 1990, GATT Doc. MTN.GNG/NG11/W/20 ¶ 31 [hereinafter Negotiating Group W20]. Exceptions to patentability for these products were seen as essential by many developing States who as previously mentioned found them essential for continued development compared to some developed countries who felt that the purpose of protecting patent rights would be too severely hurt in those areas. *Id.* ¶ 35.

As strongly as the developed countries argued the need for non-discrimination provisions within TRIPs, the developing countries expressed their desire for a continuance of compulsory licenses to allow for governments to adjust to their State's needs.<sup>274</sup> The Members may have purposefully left Article 30 ambiguous as to satisfy all parties and finish negotiations.<sup>275</sup> Countries expressed concern during the negotiations that phrases such as the "‘legitimate’ interest of the patent owner and of third parties" should be defined so as to provide more certainty in application.<sup>276</sup> Other countries such as Brazil wished for TRIPs to provide "greater flexibility for the patent system in order to take account of the special needs of developing countries."<sup>277</sup>

When interpreting the interaction between Articles 27 and 30, an essential foundation that one must consider is that "Article 27 of the TRIPs Agreement allows a country to deny intellectual property protection in a few, narrowly defined areas, and in other situations create a unique system in their country for regulating the patentability of certain products."<sup>278</sup> The non-discrimination clause therefore, "does not take away the rights of a country to regulate a certain product; it just recognizes the unique need of certain countries to regulate in a manner most beneficial to their country."<sup>279</sup>

In discussing the field of technology exception, the Panel differentiated between the ability to discriminate in certain product areas and the illegality of discrimination in fields of technology.<sup>280</sup> Though the Panel provided no theoretical example to explain the difference between product areas and fields of technology, this distinction may lie within the definition of Article 30 itself because with the Panel accepting the EC's "limited exceptions" definition of "narrow, small, minor, insignificant or restricted," a "limited exception" becomes an exception for a single product or single genre of products within the pharmaceuticals field.<sup>281</sup> Sweeping legislation that provided for an exception for all pharmaceutical products would probably not pass the "limited exceptions" or

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274. Negotiating Group W32r2, *supra* note 269, at 98–103. Developed countries countered the developing countries by demanding that compulsory licenses have express limitations so as to limit abuse. Negotiating Group on TRIPs, Meeting of Negotiating Group on 16–19 May 1988, June 21, 1988, GATT Doc. MTN.GNG/NG11/W/7 ¶ 12.

275. Negotiating Group on TRIPs, Meeting of Negotiating Group on 5–8 July 1988, Aug. 29, 1988, GATT Doc. MTN.GNG/NG11/W/8 ¶ 37.

276. *Id.*

277. Negotiating Group on TRIPs, Meeting of Negotiating Group on 17–21 Oct. 1988, Nov. 30, 1988, GATT Doc. MTN.GNG/NG11/W/10 ¶ 9.

278. Kruger, *supra* note 31, at 201.

279. *Id.* at 201–02.

280. See Canada—Generic Medicines, *supra* note 13, ¶ 7.92.

281. See *id.*



non-discrimination test, but an exception for a single product or a couple of products within the pharmaceuticals field would presumptively pass the limited exceptions test and the field of technology element of non-discrimination.<sup>282</sup> Such a decision in itself shows the Panel's willingness to allow exceptions for certain products under Article 30 as long as the exception meets the balancing tests.<sup>283</sup>

This interpretation of Article 27's relation to Article 30 is even more supported in the period following the Doha Declaration.<sup>284</sup> This period has seen even the most ardent supporters of very limited exceptions to Article 30 loosening their positions, with the United States and the EC both suggesting what they consider legal methods under Article 30 (and thereby Article 27) to fulfill the pharmaceutical needs of developing countries.<sup>285</sup> The stricter of the two, the American approach, called for allowing a:

developing country Member having sufficient manufacturing capacity in the pharmaceutical sector to export needed pharmaceuticals to a developing or least-developed country that is afflicted by a public health problem, especially those resulting from HIV/AIDs, malaria, tuberculosis, and other epidemics; and has insufficient or no manufacturing capacity in the pharmaceutical sector.<sup>286</sup>

This proposal truly weighs the objectives in Article 7 TRIPs evenly—contributing to the promotion of innovation by strictly limiting the impact of the exception; promoting the transfer and dissemination of technology by allowing a developing Member State with the required

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282. See *id.* ¶¶ 7.92–7.105. As discussed earlier, the Panel in Canada—Generic Medicines in fact allowed the regulatory review exception calling it limited to the special circumstances imposed by the need for government review, but also, in denying the “stockpiling exception” went through a thorough interest analysis, only declaring the “stockpiling exception” in violation of TRIPs on these facts.

283. See *id.*

284. Haag, *supra* note 263, at 954–60.

285. *Id.* The United States has also pressured some of its pharmaceutical companies to provide lower priced pharmaceuticals to developing States in President Clinton's executive order of May 10, 2000 and the Access to AIDS Treatment Act of 2001. Rosalyn S. Park, *The International Drug Industry: What the Future Holds for South Africa's HIV/AIDS Patients*, 11 MINN. J. GLOBAL TRADE 125, 138, 152 (2002).

286. Haag, *supra* note 263, at 955 (quoting OFFICE OF THE UNITED STATES' TRADE REPRESENTATIVE, PARAGRAPH 6 OF THE DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH (2002), available at <http://www.ustr.gov/sectors/doha-trips-graph6.PDF>). Such a concession by the United States seemingly undercuts the arguments that having Articles 30 and 31 bound by the non-discrimination clause of Article 27.1 will limit the ability of Member States to provide for the individual circumstances of their countries because such an exception as proposed by the United States directly addresses and counters the problems and concerns of those detractors.

production ability to manufacture the medicine for other developing Members as well as helping to provide the medicine to those in need; limiting the exception so as to strictly advantage the producers and users of the technology evenly; and is conducive to social and economic welfare of both those in need of medicines as well as the economic need of the innovator states.<sup>287</sup> If two Member States that have proven their dedication to adhering strictly to the text and meaning of TRIPs by filing complaints to the DSB against what they considered discriminatory national patent laws agree to the need for and legitimacy of exceptions even within the framework that Article 30 does not create an exception to non-discrimination under Article 27.1, perhaps the Article 27.1 superiority theory does not create some of the conflicts proposed.<sup>288</sup>

Additionally, some countries who signed TRIPs have valid concerns that other countries may discriminate against their products via field of technology because other countries that strongly objected to including such language in TRIPs or prior to TRIPs had systems that disallowed patents in certain fields.<sup>289</sup> If TRIPs is truly meant to be an international agreement that harmonizes patent law at a minimum level of protection then the non-discrimination clauses must not allow countries to have exceptions for purely economic protectionist reasons.<sup>290</sup> It is easy to imagine a situation where if the non-discrimination clause did not apply to exceptions under Articles 30 and 31 that a state could use an exception as a tool to better their economic well-being at the expense of another State whether it be as to a certain technological field or across many levels. The Panel echoed this concern in *Canada—Generic Medicines* in explaining that if a broad reading of Article 30 were allowed, countries could extend the discrimination beyond a possible valid use regarding field of technology to discriminate against products that tended to be made by foreign producers.<sup>291</sup> Using such a discriminatory exception may benefit the local social welfare of the State that uses the exception, but a purpose of the TRIPs Agreement as provided for in its preamble is “to reduce distortion and impediments to international trade, and taking

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287. TRIPs Agreement, *supra* note 1, art. 7; see Cann, *supra* note 234, at 807.

288. Champ & Attaran, *supra* note 9, at 386–91 (proposing that having Articles 30 and 31 within Article 27.1 is constraining on their purpose, which is to provide exceptions to TRIPs). The United States applied for a Panel decision in the Brazil—Local Working Dispute but later settled while the EC pursued their claim to a decision by the Panel in *Canada—Generic Medicines*.

289. Negotiating Group W20, *supra* note 273, ¶ 31.

290. Kruger, *supra* note 31, at 202.

291. See *Canada—Generic Medicines*, *supra* note 13, ¶¶ 7.92–7.105. Presumably, discrimination against place of invention or products that tended to be from foreign producers that could fall under the Canadian exceptions would be invalid under the Article 27.1 guarantee of non-discrimination as to place of invention or products imported or locally produced.

into account the need to promote effective and adequate protection of intellectual property rights."<sup>292</sup> If the exceptions provisions are understood to automatically rid a State of all obligations under the TRIPs Agreement and are also given a broad reading so as to allow for their frequent use, what point would the TRIPs Agreement have, especially if its greatest achievement is establishing the first uniform minimum standards for intellectual property at the international level?<sup>293</sup>

As earlier stated, an exception that meets the "limited exceptions" test under Article 30 should also satisfy the non-discrimination standard against fields of technology element.<sup>294</sup> Article 30 is entitled *Exceptions to Rights Conferred* and upon a quick review through Section 5, only Article 28 uses the language "Rights Conferred"—which happens to be the title of the Article.<sup>295</sup> The similarities in the language in Articles 28 and 30 further link them together because Article 28.1 states "a patent shall *confer* on its owner the following *exclusive rights*" and Article 30 states "members may provide limited exceptions to the *exclusive rights conferred* by a patent" (emphasis added)<sup>296</sup> Such strikingly similar language about the conferring of exclusive patent rights is found nowhere else within TRIPs.<sup>297</sup>

Additionally, Article 30 does not actually eliminate the availability of patents, it just restricts their use in limited circumstances.<sup>298</sup> Article 28 does not confer availability or non-discrimination as an exclusive right conferred by a patent, but simply lists the rights of a patent holder.<sup>299</sup> Nor does Article 27.1 establish non-discrimination as an exclusive right conferred by the patent holder, but instead it lists the general non-discrimination standard for the availability of patents and the enjoyability of patent rights.<sup>300</sup> This non-discrimination standard is expressly subjected to three articles within TRIPs so the question becomes, if Article 27 were subject to the exceptions of Article 30, why did the authors of this treaty not include Article 30 in this listing?<sup>301</sup> Because the non-discrimination standard is not an exclusive right, Article 30 cannot limit non-discrimination because Article 30's text only allows it to pro-

292. TRIPs Agreement, *supra* note 1, pmbl.

293. TRIPs FAQs, *supra* note 19.

294. Canada—Generic Medicines, *supra* note 13, ¶ 7.92.

295. TRIPs Agreement, *supra* note 1, arts. 28, 30.

296. *Id.*

297. *Id.*

298. See Weissman, *supra* note 169, at 1108–12.

299. TRIPs Agreement, *supra* note 1, art. 28.

300. *Id.* art. 27.1.

301. *Id.* Article 27.1 explicitly subjects the non-discrimination clause to "paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article [Article 27]."

vide exceptions to exclusive rights.<sup>302</sup> The availability and enjoyability are further connected together by a close textual analysis which shows the “shall be” between “patents” and “available” in the non-discrimination clause actually silently carries over because of the conjunction “and” so as to make the text read: “patents shall be available and patent rights [shall be] enjoyable without discrimination.”<sup>303</sup> Perhaps this was the negotiating parties attempt to ensure that the non-discrimination standard applied before and after the awarding of a patent.<sup>304</sup> An open concern of the parties while negotiating the treaty and since its inception has been that States would use exceptions to patent rights in a discriminatory manner.<sup>305</sup> The WTO DSB has looked unfavorably on suggestions that exceptions to non-discrimination rules can be used for a discriminatory purpose.<sup>306</sup> Article 27.1 TRIPs should not be treated any differently than non-discrimination standards in other TRIPs provisions or WTO Agreements. Therefore, Article 30 does not operate within Article 27, but only within Article 28, and the non-discrimination clause should apply.<sup>307</sup>

302. *Id.* arts. 27, 30. *See* Weissman, *supra* note 169, at 1112. “Article 30 would not permit a no-patent system. Even if such a system could be justified under the ‘unreasonable prejudice’ clause, Article 30 only allows for exceptions ‘to the exclusive rights conferred by a patent,’ meaning the patent itself must initially be granted.” *Id.* In other words, Article 27 still guarantees the availability of patents, even with the invocation of an Article 30 exception. *See id.* This analysis follows because the text of Article 30 limits the provision from impacting the availability and presumably the non-discrimination protection of Article 27.1. *See id.*

303. *See* TRIPs Agreement, *supra* note 1, art. 27.1; Champ & Attaran, *supra* note 9, at 386.

304. Gervais, *supra* note 7. The non-discrimination clause did not appear in the TRIPs negotiating history until the final proposed draft so the negotiating history does not address the exact textual meaning. Negotiating Group W32r2, *supra* 269, at 106. Many parties raised overriding concerns about the need for a non-discrimination standard in the final agreement. The non-discrimination clause may be unique to the final TRIPs text, but a separate non-discrimination requirement is mentioned in the negotiating history. Negotiating Group on TRIPs, Meeting of Negotiating Group on 11, 12, and 14 Dec. 1989, Jan. 23, 1990, GATT Doc. MTN.GNG/NG11/W/17 ¶ 51 [hereinafter Negotiating Group W17]; Negotiating Group on TRIPs, Meeting of Negotiating Group on 30 Oct.—2 Nov. 1989, Dec. 4, 1989, GATT Doc. MTN.GNG/NG11/W/16 ¶ 9; Negotiating Group on TRIPs, Meeting of Negotiating Group on 12–14 July 1989, Sept. 12, 1989, GATT Doc. MTN.GNG/NG11/W/14 ¶ 51.

305. Negotiating Group W10, *supra* note 277, ¶ 11; *see* Canada—Generic Medicines, *supra* note 13; *see generally* Negotiating Group W17, *supra* note 304; Negotiating Group W16; Negotiating Group on TRIPs, Meeting of Negotiating Group on 11–13 Sept. 1989, Oct. 26, 1989, GATT Doc. MTN.GNG/NG11/W/15; Negotiating Group W14. The text truly addresses this concern because the parties were not just worried about the very availability of a patent but also that exceptions such as compulsory licenses would be used in a discriminatory way.

306. *See supra* Parts III, V, and VI C, regarding the application of national treatment and most favoured nation status under TRIPs. Discrimination is a restriction on trade and generally not permitted by the WTO.

307. *See supra* Parts III, IV, V, and VI.

Another analysis that points to the inapplicability of Article 30 to Article 27.1 is the public international law maxim *lex specialis derogat legi generali* "which provides in essence that where a general legal provision conflicts with a specific legal provision, the specific legal provision governs."<sup>308</sup> One can turn to this method because the WTO Dispute Settlement Understanding allows for customary rules of public international law to guide in the interpretation.<sup>309</sup> Some scholars argue under this point that Article 27.1 is a general proposition and Articles 30 and 31 are specific propositions, so when in conflict with Article 27.1, Articles 30 and 31 control.<sup>310</sup> For *lex specialis* to apply, however, both provisions must pertain to the same subject matter.<sup>311</sup> Article 30, the specific provision, provides for exceptions to exclusive rights conferred, while Article 27.1 applies to non-discrimination as to the enjoyability of patent rights. Because the non-discrimination clause guarantees non-discrimination and does not dictate what exclusive rights a patent confers, Article 30 is not an exception to it and deals with different subject matter.<sup>312</sup> Therefore, *lex specialis* does not apply to the relationship between Articles 27.1 and 30.<sup>313</sup> It appears that *lex specialis* applies to the relationship between Articles 28 and 30, however, because Article 28 generally dictates what rights a patent confers its owner while Article 30 provides exceptions to the use of those rights.<sup>314</sup>

#### D. Avoiding the Problem All Together

Article 30 does not provide exceptions to Article 27.1, but this does not mean that all is lost when making exceptions for certain products that can treat health crises. This section addresses those concerns with some reasonable alternatives that work within the treaty as it is currently written. This section will address the certain product areas exception as

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308. Champ & Attaran, *supra* note 9, at 387.

309. Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, WTO Agreement, Annex 2, art. 3, in the Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 321, 334 (World Trade Organization, 1999).

310. Champ & Attaran, *supra* note 9, at 387.

311. See Otto Sandrock, "Handcuffs" Clauses in International Commercial Contracts: Basic Reflections on the Autonomy of the Parties to Choose the Proper Law for Their Contracts, 31 INT'L LAW. 1105, 1105-09. Sandrock explores whether *lex specialis* applies to the situation when the general rule—a handcuffs clause which generally limits certain causes of action, conflicts with a choice of law clause that picks a law that allows for a cause of action the handcuffs clause denies. Both the handcuffs and choice of law clauses address one single issue—which law applies to a cause of action.

312. See *id.*

313. See *id.*

314. See *id.*; TRIPs Agreement, *supra* note 1, arts. 28, 30.

discussed in *Canada—Generic Medicines*, the “circumvention method” and the “security exception.”<sup>315</sup>

As previously mentioned, “Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas.”<sup>316</sup> The limitation on exceptions “does not take away the rights of a country to regulate a certain product; it just recognizes the unique need of certain countries to regulate in a manner most beneficial to their country.”<sup>317</sup> “It can be argued that an exception could be made for those particular pharmaceuticals aimed at the prevention and treatment of HIV-AIDS. The apparent distinction between a ‘field of technology’ and a ‘certain product area’ would justify the imposition of such an exception.”<sup>318</sup> Thus, by following the *Canada—Generic Medicines* standard, a state can achieve its goal of providing pharmaceuticals to alleviate health crises, so long as its exceptions to patent rights are directed at a certain product or products.<sup>319</sup>

The “circumvention method” allows a Member to avoid the consequences of the non-discrimination clause by fitting a situation into the public health exception found in Article 27.2.<sup>320</sup> The first sentence in Article 27.1 grants the availability of patents and subjects said availability to Articles 27.2 and 27.3.<sup>321</sup> The second sentence of Article 27.1 ensures non-discrimination as to the availability of patents.<sup>322</sup> If a Member State qualifies for an exclusion to patentability under Article 27.2, the non-discrimination clause would presumably not apply because there would be no right to patentability in those circumstances.<sup>323</sup> Article 27.2 explicitly says that States can exclude from patentability, “inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal, or plant life or health...”<sup>324</sup> This language may move health issues into the realm of public ordre and morality,<sup>325</sup> creating an

315. Cann, *supra* note 234, at 822. Cann uses the term “security exception,” while this author uses the term “circumvention method.”

316. *Canada—Generic Medicines*, *supra* note 13, ¶ 7.92 (emphasis added).

317. Kruger, *supra* note 31, at 201–02.

318. Cann, *supra* note 234, at 815.

319. See *Canada—Generic Medicines*, *supra* note 13 ¶ 7.92; Cann, *supra* note 234, at 815; Kruger, *supra* note 31, at 201–02.

320. Cann, *supra* note 234, at 811; Patrick L. Wojahn, *A Conflict of Rights: Intellectual Property Under TRIPS, the Right to Health, and AIDS Drugs*, 6 UCLA J. INT’L L. & FOR. AFF. 463, 480 (2002).

321. TRIPs Agreement, *supra* note 1, arts. 27.1–27.3.

322. *Id.* arts. 27.1.

323. *Id.*

324. *Id.* art. 27.2.

325. Cann, *supra* note 234 at 811 (citing S.K. Verma, *TRIPS and Plant Variety Protection in Developing Countries*, 12 EUR. INTELL. PROP. REV. 281, 281 (1995) who believes “the

exception for public health that avoids the non-discrimination provision. "As a result, Article 27.2 arguably permits a nation to deny patent protection to one or more pharmaceutical products if there is a legitimate health reason to prevent their commercial exploitation within that nation."<sup>326</sup>

A final exception, the "security exception" escapes the patents section completely and moves to Article 73 of the TRIPs Agreement, which states that nothing in the TRIPs Agreement prevents a Member from taking any action "which it considers necessary for the protection of its essential security interests . . . taken in time of war or other emergency in international relations."<sup>327</sup> This type of article is considered "universal" and relieves a State from all substantive obligations under TRIPs.<sup>328</sup> GATT Article XXI holds a comparable security exception, which has been invoked to justify everything from restrictions for the protection of the Swedish footwear industry, to the direct intervention of the affairs of another State.<sup>329</sup> A health crisis can become a very destabilizing event that can destroy social, economic, and political structures.<sup>330</sup> AIDS provides an example of such a crisis, which both the UN Security Council and the U.S. Central Intelligence Agency has labeled as security threats.<sup>331</sup> Through the Article 73 security exception, both developing and developed countries could produce generic medicines for those States whose health crises have created a security threat for their own country.<sup>332</sup>

## VII. CONCLUSION

The actual theory and reasons behind the enactment of the TRIPs Agreement are controversial and the ambiguous nature of the treaty compounds this conflict. The case studies explored in this Note illustrate the balancing acts and high theory that comprise every dispute on this subject and the never ending nature of social welfare debates. Understandably, because all the parties to the TRIPs Agreement held very different interests, the language of the treaty had to be ambiguous and open to many interpretations so as to please all the parties involved.

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use of such language . . . transforms health-related concerns into 'moral and public order issues' . . . and thus incorporates 'overriding social, ethical, and moral considerations' into the 'patent regime'").

326. Cann, *supra* note 234, at 811; *see also* Wojahn, *supra* note 320, at 479-80.

327. TRIPs Agreement, *supra* note 1, art. 73(b)(iii); Cann, *supra* note 234, at 822.

328. Cann, *supra* note 234, at 822 (quoting JOHN H. JACKSON, *WORLD TRADE AND THE LAW OF GATT* 537-38 (1969)).

329. *Id.* at 823-25.

330. *Id.* at 827.

331. *Id.* at 828, 830.

332. *Id.* at 832.

The importance of the TRIPs Agreement should not be discounted—it is the first time that the international community was able to decide on uniform minimum standards for intellectual property rights and a judicial enforcement mechanism for those standards. Therefore, when approaching problems that arise within TRIPs, Member States must honor the text and purposes of the agreement. In doing so, any interpretation of the text when dealing with the problem should begin with an analysis of the text to see how the problem fits into the agreement and it should not begin with looking at the problem and seeing how to make the treaty conform to it.

Such an analysis leads to this Note's conclusion—TRIPs Section 5 Article 27.1 is the foundation and guiding principle of the patents section. Within Section 5, Article 27.1 is only subject to the provisions expressly listed by Article 27 as a whole. The desire to prevent non-discrimination against patents due to place of invention, field of technology, and whether imported or locally produced was a driving force behind the development of a uniform patent system because many Member States were not respecting the patent rights of companies from other States and this was becoming a barrier to the furtherance of international trade. In providing exceptions to the exclusive rights granted to a patent owner under Article 28, it is dubious that many of the Member States who signed TRIPs would have agreed that such exceptions can be implemented in a discriminatory manner because this would in effect negate the very purpose of TRIPs, especially if the exceptions are ever given as broad of a scope as advocated by some commentators.

AIDS and other medical crises that have inspired so many to comment on TRIPs are truly global tragedies and all Member States of the WTO should help their fellow Members solve these dilemmas. But in solving medical crises problems, the answer is not to throw away the bargained for provisions of the TRIPs Agreement. The TRIPs Agreement already provides a perfectly plausible framework within its text to achieve global social policy goals and protection of IPRs. This framework is found in the interaction between Articles 27, 28, 30, 31 as supplemented by Articles 7, 8, and 73.